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In The

Supreme Court of the United States

October Term, 1996

DELORES HAWKINS,

Petitioner,

v.

McNEIL PHARMACEUTICAL,

Respondent.

Petition For Writ Of Certiorari To The District Of Columbia Court Of Appeals

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Is 21 U.S.C. § 352(a), which provides that a drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular, unambiguous on its face, or is its language so complex and technical that expert testimony or judicial guidance is required to explain its meaning to a jury?

Does the District of Columbia Court of Appeals' ruling prohibiting the trial court from taking judicial notice of Federal Food and Drug Administration regulations violate the command of 44 U.S.C. § 1507?

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PETITION FOR WRIT OF CERTIORARI

Delores Hawkins respectfully prays that a writ of certiorari issue to review the judgment and opinion of the District of Columbia Court of Appeals (D.C. Court of Appeals) entered in this proceeding on December 23, 1996, in order to resolve the conflict between the D.C. Court of Appeals' opinion and opinions of the United States Supreme Court, Federal Circuit Courts of Appeals for the Second and Seventh Circuits and United States District Court opinions interpreting 21 U.S.C. § 352(a) and 44 U.S.C. § 1507.[1]

OPINIONS BELOW

The Memorandum Opinion of the D.C. Court of Appeals that gives rise to this Petition is reprinted in Appendix A hereto ("App. A").[2] The Order of the D.C. Court of Appeals, dated April 21, 1997, denying Plaintiff's Petition for Rehearing *En Banc* is reprinted in Appendix B hereto ("App. B").

JURISDICTION

Jurisdiction is invoked under 28 U.S.C. § 1257. The D.C. Court of Appeals issued its Memorandum Opinion

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[1] For purposes of review, the D.C. Court of Appeals is defined as "the highest court of a state." 28 U.S.C. § 1257(b).

[2] Specific page cites within each Appendix will be referenced, for example, as "App. 36a" or "App. 1b."

on December 23, 1996 (App. A). Petitioner Hawkins filed a timely Petition for Rehearing *En Banc* on January 6, 1997 (reprinted in Appendix C hereto). On April 21, 1997, the D.C. Court of Appeals issued an Order denying the Petition for Rehearing *En Banc* (App. B), and on May 19, 1997, the D.C. Court of Appeals granted Petitioner's motion for a stay of the issuance of the mandate for a period of thirty (30) days until May 28, 1997.

STATUTES INVOLVED IN THE CASE

FEDERAL STATUTES

21 U.S.C. § 352(a):

Misbranded drugs and devices

A drug or device shall be deemed to be misbranded –

False and misleading label

(a) If its labeling is false or misleading in any particular.

21 U.S.C. § 331(b):

Prohibited acts

The following acts and the causing thereof are prohibited:

* * *

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

18 U.S.C. § 1001:

Statements or entries generally.

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both.

44 U.S.C. § 1507:

Filing document as constructive notice; publication in Federal Register as presumption of validity; judicial notice; citation

* * *

The contents of the Federal Register shall be judicially noticed and without prejudice to any other mode of citation, may be cited by volume and page number.

STATEMENT OF THE CASE

Petitioner Delores Hawkins, individually and as the Personal Representative of the Estate of her deceased mother, Elva Mae Gilliam, sued defendant McNeil Pharmaceutical ("McNeil") in the Superior Court for the District of Columbia. The Complaint alleged both negligence and strict liability counts against McNeil (App. 3a). Elva

Mae Gilliam died from acute liver failure on June 9, 1990 (App. 2a).

The jury found that Mrs. Gilliam's death was proximately caused by the prescription drug, Parafon Forte DSC (chlorzoxazone) (App. 3a) and, in response to an interrogatory, found that the drug was misbranded because its labeling[3] was false and misleading (App. 3a-4a). This drug, a muscle relaxant, was developed, marketed and sold by McNeil. The drug was misbranded and contained false and misleading statements in its labeling from the first day it was introduced into the stream of commerce. Among the information not included in the drug's labeling was the fact that Parafon Forte DSC was toxic to the liver and could cause death from liver failure.

Plaintiff introduced uncontroverted evidence at trial that McNeil had included numerous false statements in the labeling of its products containing chlorzoxazone. The labeling falsely stated the number of reports of liver damage McNeil had received (App. 17a); failed to disclose positive rechallenge tests contained in McNeil's own files, which proved conclusively that the drug was toxic to the liver (App. 16a-17a); and misrepresented the number of deaths attributed to liver damage and the causes of death of which McNeil was aware.

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[3] "Labeling" is a defined term under the Food, Drug & Cosmetics Act in 21 U.S.C. § 321(m) and includes not only the label on the container but any written matter accompanying the product. *United States v. Diapulse Mfg. Corp. of America*, 389 F.2d 612 (2d Cir. 1968), *cert. denied*, 88 S.Ct. 2059, 392 U.S. 907, 20 L.Ed.2d 1365.

McNeil's labeling also suggested that the liver failure of persons taking chlorzoxazone was due to causes other than chlorzoxazone. For example, the labeling contained information suggesting that one patient had cancer of the liver, rather than liver damage from chlorzoxazone. However, the patient's treating physician testified at trial that there was no evidence that his patient had ever had liver cancer (App. 18a).

Uncontroverted evidence was also adduced at trial that in its initial submission to the FDA, McNeil failed to inform the FDA that in the first clinical trial with the drug in 1956, fourteen out of fifteen patients who were administered the drug had abnormal liver function test results which evidenced liver toxicity (App. 8a).[4] This

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[4] In fact, despite repeated requests from the FDA that it include an adequate warning on liver toxicity for its chlorzoxazone-containing drugs, McNeil refused to publish an adequate warning until 1995. The warning was forthcoming only after the FDA received a Citizen's Petition from Petitioner's counsel which alerted the FDA to the same evidence which was presented at trial. The FDA Response to the Citizen's Petition is reprinted in Appendix D, attached hereto.

After conducting an investigation, the FDA determined that criminal prosecution against McNeil would be barred by the statute of limitations because of the length of time that had passed (App. 3d). The FDA did determine, however, that chlorzoxazone can demonstrate hepatocellular toxicity (App. 5d). To help ensure that the revised warnings got the proper attention from health care professionals, the FDA published articles containing the revised warning in both the January 1996 *FDA Medical Bulletin* and the December 27, 1995, issue of the *Journal of the American Medical Association* (App. 7d). Thus, once the FDA received the very evidence submitted at trial and contacted McNeil, McNeil voluntarily changed its labeling.

information was never disclosed in chlorzoxazone's labeling and never disclosed to the FDA (App. 9a). It was first disclosed to the FDA by the Citizen's Petition.

After a lengthy trial in May and June of 1993, the jury found in Petitioner's favor and against McNeil on strict liability and negligence counts. The jury awarded Mrs. Hawkins $1.5 million in compensatory damages and $2.5 million in punitive damages. McNeil timely appealed and Mrs. Hawkins timely cross-appealed.

The D.C. Court of Appeals reversed the trial court and remanded the case for entry of judgment in favor of McNeil. In so ruling, the D.C. Court of Appeals held:

> " . . . [W]e hold that Hawkins was required to present expert testimony concerning the interpretation of the statutes and regulations relied upon by her, so that the jury would be guided in its application of those sources to the conduct at issue in this case. . . . "

(App. 37a). The D.C. Court of Appeals further held:

> " . . . Likewise, 21 U.S.C. § 352 (1958) appears straightforward on its face. But lay jurors may not understand, since it is not apparent on the face of the statute, that the statute is supplemented in great detail by the regulations of 21 C.F.R. §§ 201.1-201.316 (1990). . . . "

(App. 40a).

Petitioner asserts that these holdings conflict with numerous rulings of federal courts and, if allowed to

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Moreover, the FDA took immediate steps to warn the medical community of the dangers this drug presented.

stand, jeopardize well-established precedent interpreting federal food and drug laws.

The D.C. Court of Appeals expressly considered the admissibility of the regulations in question and stated that they were improperly judicially noticed. The Court of Appeals also held that the jury had improperly found that these regulations had been violated since there was no expert testimony introduced to explain how McNeil had breached the duty imposed upon it by the regulations (*see* App. A).

Petitioner directly challenged the Court of Appeals' ruling as inconsistent with the unambiguous commands of 21 U.S.C. § 352 in her Petition for Rehearing *En Banc* (App. C).[5] The federal question was first called to the attention of the D.C. Court of Appeals in the Petition for Rehearing *En Banc*.[6] Petitioner informed the D.C. Court of

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[5] The trial court, in deciding questions of federal law, found that 21 U.S.C. § 352(a) was not ambiguous and took judicial notice of the statute and its regulations, as required by 44 U.S.C. § 1507.

[6] There was no reason to assert the federal questions contained herein before that time because the trial judge had adopted the Petitioner's position, after first reviewing the statutes and regulations and hearing argument from both parties thereon. The trial judge took judicial notice of the statutes and regulations and instructed the jury on the law, as was her duty. The trial judge could have responded to any questions the jury may have had with respect to the statutes and regulations and their meanings. Notwithstanding this fact, the D.C. Court of Appeals afforded the trial judge no opportunity to correct any error of law; rather, the appellate court reversed and remanded the judgment back with instructions to enter judgment on behalf of McNeil (App. 44a).

Appeals that the Supreme Court and federal courts had consistently found that there was nothing indefinite or ambiguous in 21 U.S.C. § 352(a) (App. 3c, n. 6). Petitioner also advised the D.C. Court of Appeals that if its opinion was allowed to stand, it would have a profound adverse effect on public safety (App. 3c).

Petitioner directed the attention of the D.C. Court of Appeals to the U.S. Supreme Court's decision in *United States v. Dotterweich*, 320 U.S. 277 (1943), and *United States v. Park*, 421 U.S. 658 (1975) (App. 3c, n. 6). Petitioner urged the court to reconsider its decision that some of the provisions of the Act and its regulations were too complex for a lay jury. Petitioner also urged the court to "delineate clear criteria by which trial courts may determine when expert testimony is required and what type of expert must be provided" (App. 10c).

The D.C. Court of Appeals declined to reconsider its position despite Petitioner's urging that it was entirely appropriate to submit statutes and regulations to a jury without the need for interpretation by expert witnesses (App. B).

REASONS FOR GRANTING THE WRIT

I. The Decision Of The D.C. Court Of Appeals Jeopardizes A Federal Regulatory Scheme That Has Been Carefully Crafted Over A Period Of 91 Years

Beginning in 1906 with the passage of the Wiley Act (1906 Pure Food & Drug Act), 52 Chap. 675, 21 U.S.C.

§§ 301-392, Congress, courts and the Food and Drug Administration have carefully crafted and interpreted the misbranding provisions of the Food, Drug and Cosmetics Act, 21 U.S.C. § 352, and its implementing regulations (hereinafter, "the Act").[7] A critical feature in the development of this scheme has been the Court's consistent recognition that the misbranding provisions of the Act convey clear and unequivocal directions regarding the labeling requirements for pharmaceuticals. This is particularly true in cases where manufacturers of pharmaceuticals obtain information regarding potentially deadly toxic side effects of their products. *Stanton by Brooks v. Astra Pharm. Prod., Inc.*, 718 F.2d 553 (3d Cir. 1983).

The D.C. Court of Appeals has now, for the first time ever, held as a matter of law that the language of 21 U.S.C. § 352(a) and its implementing regulations is too complex, vague and subject to differing interpretations to be understood by a lay juror. Although the Court conceded that 21 U.S.C. § 352(a) (1958) appears "straightforward on its face," it nonetheless noted that "lay jurors may not understand, since it is not apparent on the face of the statute, that the statute is supplemented in great detail by the regulations of 21 C.F.R. §§ 201.1-201.316 (1990)" (App. 40a). The Court went on to hold that, without an explanation by an expert qualified in regulatory matters, a lay jury cannot be trusted to draw the

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[7] A comprehensive review of the Food, Drug and Cosmetics Act may be found in McClellan, Tate & Eaton, "Strict Liability for Prescription Drug Injuries: The Improper Marketing Theory," 26 ST. LOUIS U.L.J. 1 (1981).

conclusion that failure to disclose potentially deadly toxic side effects of the drug constitutes misbranding.

Without identifying any specific provision of the Act or its implementing regulations which it considered to be ambiguous, the D.C. Court of Appeals has thus held that the misbranding provisions of the Food, Drug & Cosmetics Act and its implementing regulations are too complex and too technical to be understood by a lay jury. To hold that these provisions are too technical and too complex to be understood by a lay jury leaves the door open for a criminal defendant to make the same argument and thus jeopardize the entire regulatory scheme.

The D.C. Court of Appeals' decision is at odds with decisions interpreting the proofs necessary to establish a violation of the Act. The leading cases interpreting the elements of proof necessary to establish a violation of the Act and its implementing regulations are *United States v. Dotterweich, supra,* and *United States v. Park, supra.*

In *Dotterweich,* this Court made clear the purposes of the Act and held that the Act is to be interpreted in a manner that protects a defenseless public from wrongdoing by purveyors of misbranded and dangerous food and drugs. Specifically, the Court stated the following:

> . . . The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct – awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to

> a public danger. United States v. Balint, 258 US 250, 66 L ed 604, 42 S Ct 301.

Id., 320 U.S. at 280-81.

The Act belongs to a special class of safety statutes enacted for the protection of the public for which the law recognizes no excuse. These statutes have been described by Dean Prosser as strict liability statutes for which no excuse is recognized and "neither reasonable ignorance nor all proper care will avoid liability." PROSSER & KEETON ON TORTS § 36, pp. 227-231 (1984); RESTATEMENT (SECOND) OF TORTS § 288A, Comment c, Illustration 1 (1965) (a copy of this section is attached hereto as Appendix E).

The foregoing reasoning was reinforced by the Court in *United States v. Park, supra,* where Chief Justice Burger, writing for a majority of the Court, quoted *Dotterweich* and noted that in interpreting the Act, the Court looked to the purposes of the Act whose purposes, the Court found, "touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self protection" (citations omitted). *Id.*, 421 U.S. at 668.

The Court went on to hold:

> . . . [T]he Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the

> public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.

Id., 421 U.S. at 672 (citations omitted).

In *Park*, the dissenting Justices argued that "before a person can be convicted of a criminal violation of this Act, a jury must find . . . evidence beyond a reasonable doubt that he engaged in wrongful conduct amounting at least to common-law negligence." *Id.*, 421 U.S. at 683. But the majority of the Court expressly rejected such a notion, stating:

> The Act does not, as we observed in Dotterweich, make criminal liability turn on "awareness of some wrongdoing" or "conscious fraud." The duty imposed by Congress on responsible corporate agents is, we emphasize, one that requires the highest standard of foresight and vigilance.

Id., 421 U.S. at 672-73. Thus, it is clear that the Court has eschewed any requirement for negligence to be found before a violation of the Act can be punished.[8]

If criminal liability need not be predicated on "awareness of wrongdoing" to prove a violation of the Act, it follows that no awareness of wrongdoing should be required and no proof of negligence should be required in a civil action to establish a violation of the

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[8] *See also Morissette v. United States*, 342 U.S. 246, 255, 96 L.Ed. 288, 72 S.Ct. 240 (1952); *United States v. Sullivan*, 68 S.Ct. 331, 92 L.Ed. 297 (1948).

Act. Of equal importance, it follows that the requirements of the statute are clear on their face and need no interpretation; otherwise, the imposition of strict criminal liability for violation would pose serious questions of due process. A statute requiring expert regulatory guidance in order to be understood is not one on which criminal liability without *scienter* can be imposed. Yet the courts have consistently recognized, following *Dotterweich* and *Park*, that no *scienter* requirement applies in criminal cases prosecuted under 21 U.S.C. § 352(a).

The D.C. Court of Appeals has now, by misadventure, interjected an "awareness of wrongdoing" requirement into a statute which was intended to be self-enforcing and to discourage wrongdoing by persons standing in a responsible relationship to the public. The D.C. Court of Appeals' attempt to impose a requirement for expert testimony before a violation of the Act can be found is thus at odds with established precedent of this Court.

As the Court of Appeals' discussion of the role of expert evidence reveals, the function the trial court anticipated such an expert would perform was one of explaining to a jury what kind and degree of information regarding toxic side effects would be necessary to trigger a duty to disclose under section 352(a). This is nothing more or less than the interposition of an "awareness of wrongdoing" or "common-law negligence" requirement into the statute, in conflict with the reasoning of *Park, supra*. As Petitioner argued below, this misconstrues the thrust of the regulatory scheme. Any failure to disclose

such information constitutes statutory misbranding.[9] There simply is no "complexity." The matter is one lay jurors – whether in civil or criminal trials – can determine simply by finding **as a matter of fact** whether the manufacturer possessed but failed to disclose information regarding toxic side effects.

Moreover, Petitioner had a right to rely on this Court's previous holdings in *Dotterweich* and *Park* as the Supreme Court is the final arbiter of federal statutes. *Arrow Automotive Industries, Inc. v. NLRB*, 853 F.2d 223 (4th Cir. 1988).[10] If litigants cannot rely on this Court's decisions in structuring their affairs, confusion and chaos will result as state courts, many of which lack experience in such matters, whittle away at hard-won safeguards belonging to the public.[11]

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[9] A single false or misleading claim or representation is sufficient to establish misbranding under the Act. 21 U.S.C. § 352(a). *See, e.g., United States v. 2000 Plastic Tubular Cases, More or Less Tooth Brushes*, 231 F.Supp. 236, 240 (M.D.Pa. 1964), *aff'd per curiam*, 352 F.2d 344, *cert. denied*, 383 U.S. 919 (1966).

[10] District of Columbia law clearly recognizes that interpretation or application of federal statutes or regulations under them is a federal question. *Messic v. Smith*, 69 A.2d 478 (Md. 1949). Note: D.C. has adopted the common law of Maryland. *Linkins v. Protestant Episcopal Cathedral Foundation of the District of Columbia*, 187 F.2d 357 (D.C. Cir. 1950).

[11] The danger of having inexperienced state courts interpreting federal statutes is evidenced by the mistakes of law the D.C. Court of Appeals made in trying to understand the meaning and reach of various federal statutes and regulations. For example, the D.C. Court of Appeals made the following statement in its opinion:

> [W]hile McNeil does not contest that the FD&C Act and FDA regulations are safety statutes, we agree

II. The D.C. Court Of Appeals' Ruling That The Trial Court Erred By Taking Judicial Notice Of Regulations Violates The Command Of 44 U.S.C. § 1507

At all times relevant hereto, 44 U.S.C. § 1507 provided in relevant part as follows:

> The contents of the Federal Register shall be judicially noted and without prejudice to any

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with its contention that the criminal statute prohibiting false statements to the government, 18 U.S.C. § 1001 (1958), which was also admitted by the trial court, was not intended to promote public safety and has no bearing on the issues presented here. *See Hubbard v. United States*, 115 S.Ct. 1754, 1761 (1995) (18 U.S.C. § 1001 "was passed at the behest of 'the Secretary of the Interior to aid the enforcement of laws relating to . . . transportation of hot oil' "). Hawkins made no attempt to justify the use of 18 U.S.C. § 1001, or 15 U.S.C.A. § 51-57 (1973 & 1993 Supp.) (prohibiting false advertisements), as applicable under the negligence *per se* principles).

(App. 29a-30a). What the D.C. Court of Appeals failed to understand is that there was a claim for punitive damages resulting in part from the willful withholding of safety information in McNeil's original application and in subsequent submissions to the FDA. In *Toole v. Richardson Merrell, Inc.*, 251 Cal.App.2d 689, 716, 60 Cal.Rptr. 398, 418; 29 A.L.R.3d 988 (1967) (actually cited by the D.C. Court of Appeals in its opinion at App. 29a), the court referred to the defendant's admitted violation of 18 U.S.C. § 1001 as justification for an award of punitive damages. Moreover, the court in *Stanton v. Astra, supra* (also cited in the D.C. Court of Appeals' opinion at App. 28a), clearly stated that failure to make required reports to the FDA could constitute improper marketing giving rise to liability. The D.C. Court of Appeals simply did not appreciate the impact of 18 U.S.C. § 1001 in the context of the regulatory scheme.

other mode of citation, may be cited by volume and page number.

At the trial of this action, Petitioner submitted applicable FDA regulations under 21 U.S.C. § 352(a), all of which were published in the Federal Register and Code of Federal Regulations, and the trial court duly took judicial notice of them, allowing them to be considered by the jury. In its opinion, the D.C. Court of Appeals held that it did not need to make a determination of whether the trial court erred in taking the mandated notice of regulations implementing 21 U.S.C. § 352(a) because there was no expert testimony to explain their meaning in any event (App. 33a-34a). This holding is in conflict with the holdings of many courts which have held that judicial notice of the contents of the Federal Register and the Code of Federal Regulations is mandatory. *Wei v. Robinson*, 246 F.2d 739 (7th Cir. 1957), *cert. denied*, 78 S.Ct. 144, 355 U.S. 879.

This conflict between a state court and the law of the land cannot be reasonably reconciled and unless this matter is cleared up by this Court, confusion will result. Therefore, review by this Court is clearly needed.

III. The Issues Raised In This Petition Have Wide-Ranging Impact On The Lives Of All Americans

In both *Dotterweich* and *Park*, the Court clearly stated the privileged and essential purposes that food and drug safety laws play in our ordered society. The Court held that they protect a helpless public from illegal conduct by suppliers of foods and drugs.

The D.C. Court of Appeals no doubt believed that its intrusion into this sacred domain of food and drug law was without long-term consequences. Students who follow food and drug law, however, know that such intrusions by courts inexperienced in such matters can lay waste to the will of the people and the Congress.

For example, an unfortunate decision by the U.S. Supreme Court in *United States v. O.A. Johnson*, 221 U.S. 488, 55 L.Ed. 823, 365 (1911), interpreting the misbranding provisions of the 1906 Act, rendered the federal authorities powerless to prevent the sale of an "elixir" containing sulfanilamide crystals which used diethylene glycol as a solvent. Diethylene glycol is the same substance contained in antifreeze. The "elixir" was sold by the Massengill Company as an antimicrobial agent. As a result of this regulatory failure, more than one hundred people lost their lives from ingesting the substance. This tragedy led to the passage of the 1938 Food, Drug & Cosmetics Act, at which time the Congress stated that one of the purposes of passage was to prevent the adulteration and misbranding of drugs.

Weaknesses in the 1938 Act, however, allowed the unapproved sale of Thalidomide, which caused birth defects in unborn children and which led to the passage of the 1962 Drug Act Amendments, 76 Stat. 780 (1962). Statutes and regulations at issue in the instant case were enacted as the product of hard-learned lessons since 1906.

No federal court has ever found 21 U.S.C. § 352(a) to be ambiguous, as evidenced by the court's holding in *United States v. 62 Packages More or Less of Marmola Prescription Tablets*, 48 F.Supp. 878 (D.Wisc. 1943), *aff'd*, 142

F.2d 107, *cert. denied*, 323 U.S. 731 (1944). The court specifically considered and rejected a claim that 21 U.S.C. § 352(a) was indefinite or ambiguous. In response to this claim, the court held as follows:

> Section 502(a), 21 U.S.C.A. 352(a), declares a drug to be misbranded if its labeling is false or misleading in any particular. Section 201(n), 21 U.S.C.A. 321(n), defines the scope of Section 502(a). There is nothing indefinite or ambiguous in Sections 201(n) or 502(a).

Id., 48 F.Supp. at 884.

Similarly, in *Ezagui v. Dow Chemical Corp.*, 598 F.2d 727 (2d Cir. 1979), the court found no ambiguity in 21 U.S.C. § 352 and stated the following:

> The failure to provide adequate warnings of known risks associated with normal use of the product, moreover, also violates the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 352, and the New York Education Law § 6815, both of which state that "A drug or device shall be deemed to be misbranded . . . if the labeling is false or misleading in any particular . . . The term 'labeling' means all labels and other written, printed, or graphic matter . . . accompanying such article."

Id., 598 F.2d at 733.

An example of the mischief inexperienced state courts can create is evidenced by the D.C. Court of Appeals' reliance on an intermediate Illinois state appellate court's opinion in *Northern Trust Company v. Upjohn*, 572 N.E.2d 1030 (Ill.App.Ct. 1991), *cert. denied*, 502 U.S.

1095 (1992) (App. 37a-39a), as support for its interpretation of federal law. The Illinois court issued its opinion without ever mentioning either the *Dotterweich* or *Park* cases. Should a state court setting forth the proofs necessary to constitute a violation of federal food and drug laws ignore the clear mandates of this Court in *Dotterweich* and *Park*? Rendering such an important opinion without regard to the consequences is analogous to the Court's unfortunate disruption of a carefully drawn regulatory scheme in *United States v. O.A. Johnson, supra*. It should not be allowed.

CONCLUSION

If the D.C. Court of Appeals is allowed to disrupt this painfully evolved regulatory scheme, food and drug laws enacted to protect the public will be weakened. These issues are of paramount importance to the safety of all of the people in the United States.

For the foregoing reasons, the petition for writ of *certiorari* should be granted.

Respectfully submitted,

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APPENDIX A

Notice: This opinion is subject to formal revision before publication in the Atlantic and Maryland Reporters. Users are requested to notify the Clerk of the Court of any formal errors so that corrections may be made before the bound volumes go to press.

DISTRICT OF COLUMBIA COURT OF APPEALS

Nos. 94-CV-1346
& 94-CV-1396

McNeil Pharmaceutical, Appellant/Cross-appellee,

v.

Delores Hawkins, Appellee/Cross-appellant,

Appeal from the Superior Court of the
District of Columbia

(Hon. Evelyn E. C. Queen, Trial Judge)

(Argued November 28, 1995
Decided December 23, 1996)

Richard A. Dean, with whom *Theodore B. Van Itallie, Jr.* was on the brief, for appellant/cross-appellee.

David T. Smorodin, with whom *Allen T. Eaton* and *Frank M. McClellan* were on the brief, for appellee/cross-appellant.

Bruce N. Kuhlik, Jennifer A. Johnson and *Marjorie E. Powell* filed a brief on behalf of Pharmaceutical Research and Manufacturers of America as *amicus curiae*.

Before Wagner, *Chief Judge*, and Steadman and King, *Associate Judges*.

King, *Associate Judge*: Three months after first ingesting a drug prescribed for muscle stiffness, Elva Mae

Gilliam suffered severe liver failure and died. This is an appeal in a products liability action filed by Delores Hawkins on behalf of the estate of Gilliam against McNeil Pharmaceutical ("McNeil") alleging that its drug product, Parafon Forte DSC (containing the drug generically known as chlorzoxazone), caused the liver failure and death of Gilliam, Delores Hawkins's mother. A jury awarded Gilliam's estate $1.5 million in compensatory and $2.5 million in punitive damages. McNeil appeals the judgment against it arguing that it is entitled to a reversal of the trial court order denying its motion for judgment as a matter of law, or in the alternative, a new trial, and contending that there was insufficient evidence to allow Hawkins's claims to be submitted to the jury. In her cross-appeal, Hawkins contends that the trial court erred in excluding, in the punitive damages phase, evidence concerning two of McNeil's other drug products and in instructing the jury that punitive damages must bear a reasonable relationship to actual damages. We reverse in McNeil's appeal and remand with instructions to enter judgment for McNeil. We dismiss Hawkins's cross-appeal as moot.

I. Background

In March of 1990, Mrs. Gilliam consulted Dr. Arthur Burgerman for treatment for numbness and stiffness in her hands. Dr. Burgerman prescribed Gilliam Parafon Forte DSC, a skeletal muscle relaxant containing chlorzoxazone.[1] Approximately three months later, on June 9, 1990, Gilliam died from liver failure.

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[1] Chlorzoxazone is a skeletal muscle relaxant that has been marketed by McNeil Pharmaceutical since 1958 under the

In July of 1991, Hawkins filed this action against McNeil, the manufacturer of Parafon Forte DSC.[2] Hawkins claimed, *inter alia*, that McNeil was negligent *per se*, based on violations of a federal criminal statute prohibiting false statements to the government, and numerous provisions of the Food Drug & Cosmetics Act ("FD&C Act") and Food and Drug Administration ("FDA") regulations. Hawkins also sought recovery based on strict product liability for McNeil's failure to adequately warn of chlorzoxazone's dangers.

After a month-long trial, the case was submitted to the jury on a special verdict form containing two liability questions and a punitive damages question. On June 24, 1993, the jury returned its verdict against McNeil. According to the special verdict form, the jury found liability by a preponderance of the evidence on both liability questions: (1) that "defendant McNeil Pharmaceutical was negligent in that it failed to give proper warning as to the effect or activities of Parafon Forte DSC and that such negligence proximately caused Elva Mae Gilliam's death," ("negligence *per se*" claim), and (2) that "defendant McNeil Pharmaceutical marketed its drug, Parafon Forte DSC and that said drug was unreasonably dangerous, without proper and adequate warnings and

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names of Paraflex, Parafon, Parafon Forte, and Parafon Forte DSC. At trial there were references to various versions of the drug; we will refer to the drug simply as "chlorzoxazone" or Parafon Forte DSC.

[2] Hawkins also named Dr. Arthur Burgerman, the Yater Medical Clinic, and other physicians who worked at the Yater Medical Clinic; however all those claims were dismissed by the trial court, and no appeal from those dismissals was filed.

misleading labeling and thereby proximately caused Elva Mae Gilliam's death," ("strict liability" claim). The jury also awarded punitive damages, finding by clear and convincing evidence that "McNeil, through its officers, agents or employees acted or failed to act willfully or out of a reckless disregard for the rights of individuals in Elva Mae Gilliam's situation."[3]

After the verdict was returned, McNeil filed a renewed motion for judgment as a matter of law, or, in the alternative, for a new trial. *See* D.C. Super. Ct. Civ. R. 50(b) (1995). Hawkins filed a motion for a new trial limited to the issue of punitive damages. The trial court denied each of the motions, and these appeals followed.

In its appeal, McNeil principally contends that the trial court erred in not entering judgment as a matter of law in its favor on both the negligence *per se* and the strict liability theories.[4] Specifically, McNeil argues that the

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[3] The trial occurred before our decision in *Woodner v. Breeden*, 665 A.2d 929 (D.C. 1995), which imposed the clear and convincing standard for punitive damages in all cases. The clear and convincing standard was applied here, without objection from Hawkins, apparently on the authority of *Raynor v. Richardson-Merrell, Inc.*, 643 F. Supp. 238, 245 (D.D.C. 1986) (elements justifying punitive damages in D.C. must be "clearly established," which in the context of product liability actions, is equated with the clear and convincing standard of proof).

[4] In the alternative, McNeil requests a new trial on all issues, contending that the trial court committed various errors, including: submitting the negligence *per se* claim to the jury through the wholesale submission of statutory and regulatory provisions; the giving of certain specified instructions; allowing testimony of a pharmacist regarding the incidence rate of liver injuries to chlorzoxazone; and submitting the punitive damages claim to the jury.

only theory of negligence that was presented was one of *per se* negligence, which was not supported by the evidence because: (1) the statutes were not appropriate for that purpose; (2) Hawkins did not establish that the statutes were violated; and (3) there was no evidence of proximate causation, because the prescribing physician did not read or rely upon the package insert and did not testify as to how he would have proceeded had he read the insert's warnings. Because the strict liability claim was also based on the alleged violation of statutes and regulations, McNeil contends that the court also erred in denying its motion for judgment as a matter of law on that claim for essentially the same reasons.

II. The trial

A. Hawkins's evidence

Hawkins's theory at trial was that McNeil withheld from the medical community in general, and Dr. Burgerman in particular, true and accurate information about chlorzoxazone's relation to liver damage. In particular, Hawkins claimed that McNeil inadequately labeled its chlorzoxazone-containing products, including Parafon

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In her cross-appeal, Hawkins urges the court to grant her a new trial on punitive damages, claiming that the trial court erred in excluding evidence relating to two of McNeil's other drug products and in instructing the jury that punitive damages must bear a reasonable relationship to actual damages. Because we conclude that the trial court erred in not requiring expert testimony concerning the meaning of the statutes, and that reversal is required on that ground, we do not reach any of the other contentions raised.

Forte DSC, from 1958 through 1990. As a basis for her negligence *per se* claim, Hawkins relied on numerous federal statutes and regulations, which she claimed had been violated. To establish that McNeil was untruthful in its labeling of chlorzoxazone, Hawkins placed considerable emphasis on three clinical studies conducted during chlorzoxazone's trial stage of development. In order to set the context of the issues that have been presented, we will review in some detail the labeling information for chlorzoxazone, the clinical studies on the drug's effect on the liver, the statutes and regulations submitted to the jury, and the testimony of Hawkins's and McNeil's witnesses at trial.

1. *Labeling*

As required by federal law, Parafon Forte DSC was distributed with an FDA-approved label, which sets forth various categories of information about the drug, including its indications, contraindications, warnings, precautions, and adverse reactions. Parafon Forte DSC's 1987 FDA-approved label, which was substantially the same for all of McNeil's chlorzoxazone-containing products, warned of the following:

> **WARNINGS**
>
> The concomitant use of alcohol or other central nervous system depressants may have an additive effect.
>
> **PRECAUTIONS**
>
> PARAFON FORTE DSC chlorzoxazone should be used with caution in patients with known allergies or with a history of allergic reactions to

drugs. If a sensitivity reaction occurs such as urticaria, redness, or itching of the skin, the drug should be stopped.

If any symptoms suggestive of liver dysfunction are observed, the drug should be discontinued.

ADVERSE REACTIONS

After more than twenty-six years of extensive clinical use of chlorzoxazone-containing products in an estimated thirty-two million patients, it is apparent that the drug is well tolerated and seldom produces undesirable side effects. Occasional patients may develop gastrointestinal disturbances. It is possible in rare instances that chlorzoxazone may have been associated with gastrointestinal bleeding. Drowsiness, dizziness, lightheadedness, malaise, or over-stimulation may be noted by an occasional patient. Rarely, allergic-type skin rashes, petechiae, or ecchymoses may develop during treatment. Angioneurotic edema or anaphylactic reactions are extremely rare. There is no evidence that the drug will cause renal damage. Rarely, a patient may note discoloration of the urine resulting from a phenolic metabolite of chlorzoxazone. This finding is of no known clinical significance.

Approximately thirty-six patients have been reported in whom the administration of chlorzoxazone-containing products was suspected as being the cause of liver damage. In one case, the jaundice was subsequently considered to be due to a carcinoma of the head of the pancreas rather than to the drug. In a second case, there was no jaundice but an elevated alkaline phosphatase and BSP retention. In this patient there

was a malignancy with bony and liver metastases. The role of the drug was difficult to determine. A third and fourth case had cholelithiasis. Diagnosis in a fifth case was submassive hepatic necrosis possibly due to abusive use of the drug for approximately one year. The remaining cases had a clinical picture compatible with either a viral hepatitis or a drug-induced hepatitis. In all these latter cases, the drug was stopped, and with one exception, the patients recovered. It is not possible to state that the hepatitis in these patients was or was not drug-induced.

2. *Clinical investigations*

a. Dr. Arthur L. Drew

In the mid-1950s, Dr. Arthur L. Drew, Associate Professor of Neurology at the Indiana University Medical Center, began a clinical study assessing the effect of chlorzoxazone on the liver. In September of 1956, Dr. Drew informed a McNeil representative of preliminary results of his study. Dr. Drew reported that after administering chlorzoxazone to fifteen patients who suffered from severe cerebral palsy, fourteen developed a numerical increase in liver function tests: an elevation of cephalin-cholesterol flocculation[5] and a positive test for bilirubin[6] in the urine. Two months later, Dr. Drew

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[5] At trial Hawkins elicited testimony that the increase in cephalin cholesterol flocculation was important because it is a serious condition indicating, among other things, abnormality in the liver cell.

[6] There was later testimony that bilirubin should not be present in the urine under normal circumstances.

reported that nine patients remained in the study, and after all were taken off chlorzoxazone for one week, four of the five patients who had notably elevated cephalin cholesterol flocculation had returned to normal. After all nine patients were again administered chlorzoxazone, seven of the nine patients developed an elevation of cephalin cholesterol flocculation within three to four weeks.[7]

In January of 1957, Dr. Drew submitted his completed clinical study and accompanying drug therapy records to McNeil. In a letter accompanying his records, Dr. Drew noted that he experienced difficulty in obtaining systematic tests from the laboratory he was using for his study. Dr. Drew concluded that he was "inclined to feel that the liver abnormalities in most cases [were] both insignificant and coincidental" and that "carefully controlled checks will fail to show any real evidence of liver damage."

In its original New Drug Application ("NDA") for chlorzoxazone, filed with the FDA in November 1957, McNeil submitted the drug therapy records for Dr. Drew's remaining nine patients, and indicated that "[i]n the series reported by Doctor Drew, there were nine patients with no side effects. One individual complained of headache and nausea while receiving the drug."

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[7] Dr. Drew reported that there were no other signs or symptoms of illness and no evidence of jaundice in any patient. He also reported that all other laboratory studies, including the thymol turbidity, total proteins, serum bilirubin, and icteric index, remained within normal limits.

b. Dr. Robert C. Batterman

After receiving Dr. Drew's reports, McNeil asked Dr. Robert C. Batterman to conduct a study of the potential effect of chlorzoxazone on the liver. Dr. Batterman's study included sixteen patients and three tests of liver function: thymol turbidity; cephalin cholesterol flocculation; and serum bilirubin. Of the thirteen patients who continued to receive medication, Dr. Batterman reported results in "three [patients with] possible abnormal readings" of liver function.[8] However, he reported possible alternative causes of the abnormal readings in all three patients.

All of Dr. Batterman's charts and clinical investigative reports, which indicated that twelve of thirteen patients showed some degree of increase in liver function, were submitted by McNeil to the FDA. Dr. Batterman's study concluded that chlorzoxazone "in dosages of 250 mg. 3 times daily for as long as 2 months of continuous therapy has no specific effect upon liver function." In its NDA, McNeil reported that Dr. Batterman's studies indicated that chlorzoxazone had "no specific effect upon the liver function."

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[8] Two of Dr. Batterman's patients were "control" patients, who did not receive chlorzoxazone. One of the fourteen patients receiving the drug discontinued medication after five days because of an "allergic reaction all over the body." While there was some indication at trial that two of Dr. Batterman's patients had withdrawn from the study, the drug therapy charts indicate that while another patient did have an allergic reaction, the therapy was not discontinued.

c. Dr. William P. Peak

Dr. Peak, a clinical investigator funded by McNeil and former Fellow of the National Institute of Arthritis and Metabolic Diseases, in conjunction with Dr. Richard T. Smith, Director of the Department of Rheumatology and the Benjamin Franklin Clinic in Philadelphia, began a clinical trial in 1956 to compare the effects of chlorzoxazone with a related drug, zoxazolamine. Dr. Peak utilized the cephalin cholesterol flocculation test.

In a hand-written letter dated June 13, 1958, Dr. Peak reported to McNeil that one of his patients had a positive liver function test after taking chlorzoxazone. Thereafter, in June of 1960, Drs. Peak and Smith published an article based on their study in the Pennsylvania Medical Journal that stated that no patients using chlorzoxazone were found to have any type or incidence of hepatoxicity[9]. Hawkins introduced evidence that McNeil knew of Dr. Peak's letter, and nonetheless used the article in its advertising and labeling of its chlorzoxazone products.

3. *Statutes and regulations*

At trial Hawkins contended that McNeil had violated numerous federal statutes and regulations. Over McNeil's objections, the trial court took judicial notice and provided the jury copies of the following federal statutes and

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[9] Hepatoxicity is defined as the "quality or property of exerting a destructive or poisonous effect upon liver cells." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (26th ed. 1981).

regulations: 15 U.S.C. §§ 51-57 (1993 Supp.) (false advertisements); 18 U.S.C. § 1001 (1959) (prohibiting false statements to the government);[10] 21 U.S.C. § 331 (1965) (prohibiting adulteration or misbranding of drugs); 21 U.S.C. § 352 (1989) (false or misleading label renders drug misbranded);[11] 21 U.S.C. § 355(b)(1) (1953) (new drug applications must include full reports of drug safety investigations); 21 C.F.R. §§ 130.30 & 130.35 (1993) (prohibiting "untrue statement" of material fact in new drug application);[12] 21 C.F.R. Pt. 201 (1985) (form and content

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[10] 18 U.S.C. § 1001 provides:

> Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly or willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be [in violation of this statute]. 18 U.S.C. § 1001.

[11] 21 U.S.C. § 352 provides:

> A drug or device shall be deemed to be misbranded –
>
> (a) False or misleading label
>
> If its labeling is false or misleading in any particular.

[12] 21 C.F.R. § 130.35(b)(7) provides:

> If the clinical or other experience reported to or otherwise obtained by the applicant has revealed any information concerning any side-effect, injury, toxicity, or sensitivity reaction, or any unexpected incidence or severity thereof which by kind, or incidence or severity is not fully disclosed in the labeling, whether or not determined to be attributable to the drug, this information shall be submitted as soon as the review reveals such facts. Such

of prescription drug advertising); 21 C.F.R. § 202.1 (1985) (content of prescription drug advertising); 21 C.F.R. §§ 310.302 and 310.303 (1993) (long-term studies, records and reports on new drugs); 21 C.F.R. § 314.8 (1983) (supplemental applications for new drugs); 21 C.F.R. § 314.12 (1985) (untrue statements in new drug application).[13] The trial court provided the jury the full text of the statutes, which contained over sixty-seven pages, copied so that some or all of the text of several other sections of the regulations, the relevance or admissibility of which had never been determined, were also included and therefore available to the jury.[14] Moreover, some of the copies of statutes included case annotations following each provision.[15]

McNeil objected to the use and submission of these statutes numerous times throughout the trial. In particular, on the opening day of trial, McNeil made a "continuing objection" to Hawkins' intention to "invok[e] a

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information shall include full reports of all available information with respect to any deaths, apparently related to drug administration whether or not determined to be attributable to the drug. Any such information previously submitted for inclusion in the new drug application or antibiotic form 5 or 6 need not be resubmitted.

[13] The record is unclear whether 21 U.S.C. § 333 was admitted; the jury did receive a copy of it. § 333 pertains to criminal penalties and fines only; it does not set forth any guidelines or standards.

[14] Examples of provisions erroneously included were those found in: 21 C.F.R. § 314.6-.7; 21 C.F.R. 314.9; 21 U.S.C. 353 (1989);

[15] These included 15 U.S.C.A. §§ 52-56 (1973 & 1993 Supp.).

federal statute as defining the standard of care." During the testimony, McNeil reiterated its objection several times, stating that it "had no objection to the court taking judicial notice of anything it wanted to take judicial notice of, but we denied the relevance and we object to their admission of exhibits into evidence and objected that they be shown to the jury." McNeil's counsel also stated: "Just so my objection is clear, I object to them coming into evidence at all, and I specifically object to these statutes and regulations being submitted to the jury."

4. *Testimony*

a. Expert testimony

Hawkins presented numerous witnesses, qualified as experts in various fields of medicine, to support her case. Dr. Patrick Joseph Dean, a physician at the Department of Pathology of the Baptist Memorial Hospital in Memphis, Tennessee, and board certified in pathology, was accepted as an expert in the field of anatomic and clinical pathology and gastrointestinal pathology. Dr. Dean opined that, based on his review of slides and medical records, Gilliam died of acute liver failure, which was caused by massive death of liver cells. While he further opined that the massive death of liver cells was caused by chlorzoxazone, Dr. Dean conceded that it is difficult, if not impossible, to distinguish drug injury from viral injury simply by looking at slides of a damaged liver.

Dr. John Golombos, a professor emeritus of medicine at Emory University and a consultant in hepatology, who was accepted as an expert in diseases of the liver, opined

that to a reasonable degree of medical certainty Gilliam suffered liver failure due to hepatitis induced by chlorzoxazone. Sustaining McNeil's objection to questions, the court did not allow Dr. Golombos to opine whether, based on his review of Dr. Drew's study, McNeil had submitted false reports to the FDA.

Hawkins also attempted to elicit testimony from Dr. Golombos regarding whether information allegedly missing from the NDA would affect the FDA's evaluation of a drug. The court limited the scope of Dr. Golombos's testimony, saying:

> You may ask [Dr. Golombos] what a physician needs, you may ask him what physicians need in treating patients, what physicians need in doing research, what physicians need in evaluating applications for new drugs, but you may not ask him if the withholding of the drug biases the FDA. You may ask would it significantly impact upon the FDA's opinion or final outcome, but you may not ask him if it would bias them.

Dr. Golombos opined, based on his review of the NDA for chlorzoxazone and the clinical records of Dr. Drew, that all significant information necessary to determine the safety of the drug was not submitted by McNeil to the FDA.

Dr. Golombos characterized Dr. Drew's clinical study as a rechallenge,[16] and stated that "the Drew study raises

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[16] A "rechallenge" is generally known as a study where a patient with an adverse reaction is taken off a drug for a period of time and then "rechallenged," or reexposed to it. If the same

serious questions regarding the effect of [chlorzoxazone] on the liver." Furthermore, Dr. Golombos opined that "the Drew study clearly indicates that the drug had a detrimental effect on the liver." Dr. Golombos also characterized the studies of Dr. Schiff and Dr. Bowers as positive rechallenges, and opined that McNeil's failure to disclose the three rechallenge tests would impair a physician's ability to exercise medical judgment. He further testified that McNeil had received the reports of the positive rechallenges prior to receiving a letter from Dr. Powers stating that "[r]eview of these records fails to demonstrate any reports with a positive rechallenge to the drug."

Dr. Golombos also addressed the Batterman study, of which he conducted his own statistical analysis. He stated that it was "unlikely that th[e] increase [in liver function] was a chance occurrence" and that the drug had a significant effect on the liver in producing an abnormal result. Moreover, he testified that the failure of McNeil to perform its own statistical analysis of the Batterman test results and to disseminate that information to the medical community would impair a physician's ability to exercise his or her independent medical judgment in deciding whether to prescribe the drug.

He further testified that a drug's reputation for safety in the medical community is primarily based on published information in the medical literature, on hearsay from colleagues who have had good or bad experiences

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reactions reappear, the rechallenge is said to show a positive correlation between the adverse reaction and the drug.

with the drug, and from information given to physicians by the representative of the drug company. Finally, based on the information he reviewed, Dr. Golombos opined that physicians had received misleading information about the affects of chlorzoxazone on the liver.

Dr. Golombos was not permitted, however, to offer any opinion on the safety of drugs, testify whether the warning given by McNeil was adequate, or to characterize the conduct of McNeil. In sustaining McNeil's objection to each question touching on these issues, the trial court ruled that Dr. Golombos was not offered or qualified as an expert for those purposes, and he was "not an expert on drug evaluation nor [did] he work with the FDA." Furthermore, Dr. Golombos was not permitted to opine as to whether McNeil had breached its statutory or regulatory responsibilities. Hawkins does not challenge the trial court's rulings on these points in its appeal in this court.

Hawkins also called Dr. Bernard Powers, accepted as an expert in gastroenterology and internal medicine, who in 1984 conducted a rechallenge on one of his patients who had been prescribed chlorzoxazone. As a follow-up to his study, Dr. Powers located fifty-five reports of adverse reactions to chlorzoxazone, nineteen of which he received from the FDA as occurring before 1970, twenty-three of which occurred as of 1983, and thirteen of which were reported in Sweden. Dr. Powers testified that McNeil's 1985 label for chlorzoxazone stated that "approximately 27 patients have been reported in whom the administration of . . . [chlorzoxazone] was suspected as being the cause of liver damage." He also testified that as of 1990, he located an additional fifteen reports of

adverse reactions in Sweden, but the chlorzoxazone's label only reported approximately thirty-six patients with adverse reactions.

Dr. Powers testified that the chlorzoxazone label "has a lot of conflicting information within it," and that because it failed to disclose at least two known positive drug rechallenges, it neglects to inform the physician on a vitally important matter. Dr. Powers, however, was not accepted as an expert on labeling of pharmaceuticals, and thus did not offer an opinion concerning the label's sufficiency.

b. Fact witnesses

Dr. Rusocoff, a retired physician who specialized in internal medicine and diseases of the chest, testified that one of his patients developed abnormal liver functions after taking chlorzoxazone, and that the patient's liver functions returned to normal when the drug was discontinued. In Dr. Rusocoff's opinion, it was "quite clear that [chlorzoxazone] had been the culprit and was responsible for creating [the] abnormalities of liver function." He reported the adverse reaction to McNeil in 1962. To establish that McNeil published false information on its labels, Dr. Rusocoff testified that his patient fit the profile of a patient described on chlorzoxazone's label. The label disclosed the patient's adverse reaction, but indicated that the patient had liver cancer. Dr. Rusocoff testified that his patient had prostate cancer, not liver cancer.

Plaintiff also called, as a fact witness, Dr. Arthur Burgerman, the physician who prescribed the drug to the decedent. A licensed physician who was board certified

in internal medicine, Dr. Burgerman prescribed Parafon Forte DSC to Gilliam in an effort to relieve numbness and stiffness she was experiencing in her arms. At trial, Dr. Burgerman testified that he first prescribed chlorzoxazone between 1968 and 1970, and at that time reviewed the drug's product labeling. Although Dr. Burgerman knew that reports of liver damage had been associated with chlorzoxazone, he did not think the drug caused liver damage, and he did not inform Gilliam that the drug had a possible association with liver damage or death.

Dr. Burgerman testified that he did not review McNeil's labeling again until sometime between Gilliam's death and the trial. In prescribing the drug during his years of practice, Dr. Burgerman stated that he "relied on a number of factors, primarily [his] own experience over many years, which had been good, plus discussions with other physicians, plus meetings [he went] to, articles [he] read, journals [he] read, [and] lectures [he] attend[ed]." Moreover, he testified that the drug's label, which he read twenty years earlier, was one of the factors that he relied upon in prescribing chlorzoxazone, as well as communications made to him by colleagues about the drug's risks and benefits. Finally, Dr. Burgerman testified that in prescribing the drug for Gilliam he "relied more on [his] own knowledge of the drug than [he] did on something that the drug company published."

Plaintiff attempted to elicit from Dr. Burgerman a response to the hypothetical question of whether, had he been aware that chlorzoxazone had the potential of causing massive liver damage to the extent of causing death, he would have prescribed the drug to Gilliam. The trial court sustained McNeil's objection to the question based

on the ground that it was speculative. The court noted that Dr. Burgerman was "not proffered as an expert," having been designated pretrial as a treating physician and not as an expert witness. The trial court ruled that "[h]ypotheticals will not be accepted" from Dr. Burgerman, and denied Plaintiff's motion, made the next day, to recall Dr. Burgerman to testify on that point.[17]

Plaintiff also presented the deposition testimony of Claudia A. White, Barry J. Cohen, Gary P. Horowitz, and Mr. Christopher Keeys. Gary Horowitz, Ph.D, McNeil's Senior Director of Affairs, testified about the results of Dr. Batterman's and Dr. Drew's studies. Mr. Keeys, President and co-founder of Clinical Pharmacy Associates, was qualified as an expert in "monitoring of drug information, including the collection, evaluation, dissemination of drug information." Mr. Keeys testified that based on his estimates, including the data from the Peak/Smith and Drew clinical studies, the total number of reported

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[17] While Hawkins generally complains of that ruling in her brief, she has not made a formal challenge, and we, therefore, do not consider it. However, we note that this court addressed a similar issue in at least two previous cases. *See Adkins v. Morton*, 494 A.2d 652 (D.C. 1985) (treating doctor, who was not listed as a Rule 26(b)(4) expert, was eligible to testify about the reasons he had not ordered home nursing care and about his opinion as to why the patient would not need such care because it "comprised knowledge and views derived not in anticipation of litigation," but rather from course of treatment); *Abbey v. Jackson*, 483 A.2d 330 (D.C. 1984) (treating physicians not experts within Super. Ct. Civ. R. 26(b)(4), were allowed to testify because they "were participants in events leading to lawsuit," thus their expertise was not developed in anticipation of litigation).

cases of toxic reaction to chlorzoxazone was actually one in 450,000 patients. The parties stipulated that the drug containing chlorzoxazone "ingested by Elva Mae Gilliam was unaltered and in the same condition as when it left the control of Defendant McNeil Pharmaceutical." Finally, Delores E. Hawkins, Gilliam's daughter, testified as to the circumstances of her mother's death.

B. Defense evidence

McNeil's witnesses, Dr. James Goddard, former FDA Commissioner, and Dr. Carroll M. Leevy, who had served ten years as a consultant to the FDA on hepatoxcity drug studies, were qualified as experts in FDA regulations and their application to labeling.[18] Drs. Goddard and Leevy testified that McNeil's labeling was fully adequate to inform prescribing physicians about the risks and benefits of the drug. Dr. Goddard testified that McNeil was at all times in compliance with FDA regulations regarding chlorzoxazone and that its labeling for the product was fully adequate. He noted there was no regulatory requirement that positive rechallenges be identified in drug labeling. Dr. Leevy also testified that there was no need to include rechallenge information in the label.

III. Legal principles

In reviewing the denial of a motion for judgment as a matter of law, this court applies the same standard as the trial court, which decides whether it must "render the

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[18] Hawkins stipulated to Dr. Leevy's qualifications, including as an expert on liver disease and FDA evaluation.

verdict mandated by law irrespective of the verdict issued by the jury." *District of Columbia v. Cassidy*, 465 A.2d 395, 397 (D.C. 1983) (per curiam); *see also Ceco Corp. v. Coleman*, 441 A.2d 940, 944 (D.C. 1982). The trial court may resolve as a matter of law factual issues only when "the facts, viewed most favorably to the nonmoving party, permit but one reasonable conclusion as to the proper judgment." *Cassidy, supra*, 465 A.2d at 391 (quoting *District of Columbia v. Cooper*, 445 A.2d 652, 655 (D.C. 1982) (en banc)). Moreover, "where there is no basis in evidence for a finding of . . . negligence, it is error to instruct on the subject and thereby submit to the jury an issue outside the evidence." *District of Columbia v. White*, 442 A.2d 159, 163 n.9 (D.C. 1982) (quoting *Montague v. Henderson*, 409 A.2d 627, 628-29 (D.C. 1979); *see also Robinson v. Washington Internal Med. Assocs., P.C.*, 647 A.2d 1140, 1144-45 (D.C. 1994) (requiring request for special verdict or general verdict with interrogatories to preserve issue in some circumstances).

A. Negligence theories

As a general rule, the plaintiff in a negligence action bears the burden of proving "the applicable standard of care, a deviation from that standard by the defendant, and a causal relationship between that deviation and the plaintiff's injury." *See Toy v. District of Columbia*, 549 A.2d 1, 6 (D.C. 1988); *see also Meek v. Shepard*, 484 A.2d 579, 581 (D.C. 1984) (citations omitted) (medical malpractice); *Jones v. Safeway Stores, Inc.*, 314 A.2d 459, 460 (D.C. 1974). In the present case, the plaintiff proceeded on theories of negligence *per se* and strict liability, which are slight variations on this general rule.

To prevail on a negligence *per se* theory, the plaintiff may, in certain circumstances and under specified conditions as discussed in Part B, rely on a statute or regulation as proof of the applicable standard of care. *See Ceco Corp., supra*, 441 A.2d at 945. Proof of "[an] unexplained violation of that standard renders the defendant negligent as a matter of law," *id.* (quoting *Richardson v. Gregory*, 108 U.S.App. D.C. 263, 266, 281 F.2d 626, 629 (1960)), so long as the violation was the proximate cause of the injuries, and the alleged injuries were of the type which the statute was designed to prevent. *See Rong Yao Zhou v. Jennifer Mall Restaurant, Inc.*, 534 A.2d 1268, 1277 (D.C. 1987); *Lewis v. Washington Metro. Area Transit Auth.*, 463 A.2d 666, 674 (D.C. 1983). If, however, the defendant puts forth evidence excusing the violation, the violation may be considered evidence of negligence rather than negligence *per se*. *See Zhou, supra*, 534 A.2d at 1274; *Ceco Corp., supra*, 441 A.2d at 945; *cf. Robinson v. District of Columbia*, 580 A.2d 1255, 1257 (D.C. 1990) (violation may be excused if the defendant demonstrates that he did "everything a reasonable person would do" to avoid that violation).

To recover under a theory of strict liability, a plaintiff must show that the product entered the stream of commerce with a design or manufacturing defect rendering it unreasonably dangerous. *See East Penn Mfg. Co. v. Pineda*, 578 A.2d 1113, 1118 (D.C. 1990). In this context,

> strict liability recognizes that some products, even if perfectly designed and manufactured, cannot be made completely safe for their intended use. RESTATEMENT (SECOND) OF TORTS, § 402A cmt. j (1965). In such cases, the defect and unreasonable danger "is the failure to attach adequate warnings to a product that, as

> designed and manufactured, may in certain circumstances cause injury."

East Penn Mfg. Co., supra, 578 A.2d at 1118 (citation omitted). Because McNeil did provide warnings of some of the adverse effects of chlorzoxazone on the liver, the issue here is not a failure to warn, but rather the *adequacy* of the warning.

Under strict liability, the duty of a manufacturer of a product *known* to be potentially harmful is one of ordinary care. *Id.* at 1118; *Russell v. G.A.F. Corp.*, 422 A.2d 989, 991 (D.C. 1980) (citing to RESTATEMENT (SECOND) OF TORTS, § 402A cmt. k (1965)). Indeed, we have noted that "a strict liability action for failure to warn is 'really nothing more than a ground of negligence liability described as the sale of a product in a defective condition, subject, however, to the defenses and other limitations on liability applicable to strict liability rather than negligence.' " *East Penn Mfg. Co., supra,* 578 A.2d at 1118 n.5 (quoting W. KEETON ET AL., PROSSER & KEETON ON THE LAW OF TORTS, § 99, at 697 (5th ed. 1984)). In other words, negligence and strict liability, in failure to warn cases, are functional equivalents in that both condition liability on the defendant's having actually or constructively known of the risk that triggers the need for a warning. Thus, the principal benefit to a plaintiff proceeding under a strict liability theory in a failure to warn case is that a defendant cannot claim contributory negligence as a defense, a circumstance not applicable in this case. *See Payne v. Soft-Sheen Prod.*, 486 A.2d 712, 721 n.9 (D.C. 1985).[19]

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[19] Assumption of the risk, however, bars recovery under either strict liability or negligence. *See Payne, supra,* 486 A.2d at 721 n. 9; *East Penn, supra,* 578 A.2d at 1119.

In sum, under either the *per se* or strict liability theories, the plaintiff must establish the applicable standard of care, show that the defendant violated that standard, and that the violation was the proximate cause of the injury. The standard of care may be established by looking to the conduct of the industry or profession in similar circumstances – in this case a reasonable pharmaceutical company – or by looking to standards embodied in statutes or regulations. *See Zhou, supra,* 534 A.2d at 1273-74; *Ceco Corp., supra,* 441 A.2d at 945.

Hawkins acknowledges that the only evidence of a standard of care presented to the jury was the standard established by the numerous federal statutes and regulations submitted to the jury. Indeed, a review of the trial transcript indicates that none of Hawkins's witnesses testified as to a standard of care. Thus, the threshold question is whether the statutes and regulations served as appropriate exclusive proof of the standard of care.

B. Statutes and regulations as proof of standard of care

We first turn to an examination of the principles governing the admissibility of statutes and regulations offered to establish a standard of care for negligence *per se* purposes. While we do not decide, with the one exception noted below, whether the trial court properly admitted the statutes and regulations considered by the jury here, we do conclude that the trial court did not adequately examine the statutes and regulations to determine whether they established a standard of care and, if

so, whether they could be understood by the jury without further guidance.

The decision to adopt from a statute a standard of care to be applied in determining common law negligence is " 'purely a judicial one, for the court to make.' " *Zhou, supra,* 534 A.2d at 1274 (quoting RESTATEMENT (SECOND) OF TORTS § 286 cmt. d at 26 (1965)).[20] In fact, a court may decline to apply negligence *per se* to a particular case "if sufficient policy considerations militate against it." *White, supra,* 442 A.2d at 164. At a minimum, however, the statute or regulation relied on must promote public safety and have been "enacted to protect persons in the plaintiff's position or to prevent the type of accident that occurred." *Joy v. Bell Helicopter Textron, Inc.,* 303 U.S.App. D.C. 1, 9, 999 F.2d 549, 557 (1993) (applying District of Columbia law and citing *Ceco Corp., supra,* 441 A.2d at 945 (other citations omitted)); *see also Zhou, supra,* 534 A.2d at 1273. The statute must also "impose specific duties on the defendant." *White, supra,* 442 A.2d at 164 (citation omitted).

Moreover, a statute or regulation offered to establish a standard for negligence *per se* purposes must not merely repeat the common law duty of reasonable care, but must set forth "specific guidelines to govern behavior." *Joy, supra,* 303 U.S. App. D.C. at 10, 999 F.2d at 558; *see also, e.g., Thoma v. Kettler,* 632 A.2d 725, 728-29 n.8 (D.C. 1993) (noting that the generality of the regulation providing

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[20] "Defining the contours of common law liability, including the duty that may have been breached in a negligence case, is a task traditionally within the purview of the judicial branch." *Zhou, supra,* 534 A.2d at 1274 (citations omitted).

that "[d]ebris and other loose materials, shall not be allowed on or under stairways" and "[s]lippery conditions on stairways shall be eliminated as soon as possible" did not differ significantly in particulars from the common law standard of reasonable care in the circumstances); *District of Columbia v. Mitchell*, 533 A.2d 629, 639 (D.C. 1987) (violation of statute requiring Department of Corrections to be "responsible for the safekeeping, care, protection, instruction, and discipline" of inmates implicitly recognized the common law duty of reasonable care and contained no specifics that could give rise to claim of negligence *per se*); *Lewis, supra*, 463 A.2d at 674 (holding that negligence *per se* instruction was not warranted where plaintiffs alleged violation in building code provision requiring neighboring property and structures be "sufficiently supported").

McNeil argues that the trial court erred in admitting the statutes and regulations received here. In particular, McNeil contends that the trial court failed to make the threshold determination that the statutes were applicable, arguing that the statutes were too complex, vague, and subject to differing interpretations to be understood and applied by a lay juror.

Hawkins responds that the trial court correctly ruled that the statutes and regulations were admissible,[21] contending that the case law does not support McNeil's

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[21] Hawkins also contends that McNeil waived this argument by failing to object to the admission of specific parts of the statutes as too complex for negligence *per se* purposes and did not object to providing the jury with copies of the statutes. However, the record indicates that McNeil entered effective objections, including its "continuing objection" to the statutes

contention that the statutes were too complex for negligence *per se* purposes. Moreover, as counsel acknowledged at oral argument, Hawkins relies on the plain meaning of the statutes, arguing that she was not required to offer expert testimony to explain their meaning. In support of that argument, Hawkins cites several cases in which FDA regulations were admitted to establish the standard of care. We think that Hawkins's reliance on those cases is misplaced because in each case cited, unlike the circumstances presented here, the violation at issue was clear and uncomplicated, and involved only a small number of readily understandable statutes. *See Stanton by Brooks v. Astra Pharm. Prod., Inc.*, 718 F.2d 553, 560 (3d Cir. 1983) (pharmaceutical company failed altogether to submit NDA for a new drug and failed to forward any of more than 200 adverse reactions to the FDA); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132 (3d Cir. 1973) (company advertised a change in the market use of

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serving as definitions of the standard of care. See Part II, A. (3). McNeil's objections clearly " 'called to the attention of the trial court . . . the question of law involved.' " *Ceco Corp., supra*, 441 A.2d at 947 (citations omitted). Furthermore, even if McNeil did not continue to phrase its objection in the same manner each time, its failure to repeat every part of its objection "may be disregarded if the party's position has previously been clearly made to the court and it is plain that a further objection would be unavailing." 9A CHARLES A. WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE, § 2553, at 411 (2nd ed.1994) (commenting on Rule 51 of the Federal Rules of Civil Procedure, which is identical to Super. Ct. Civ. R. 51); *cf. Lewis v. Washington Metro. Area Transit Auth.*, 463 A.2d 666, 672-73 n. 14 (D.C. 1983) ("unduly harsh to penalize appellants" under Rule 51 "for their imperfectly timed request," where the trial judge had adequate opportunity to consider and act upon the request).

drug but failed altogether to submit NDA for the new purpose as required by the FDA); *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960) (incorrect diameter stated on surgical nail label could be negligence *per se* under FDA statute prohibiting "misbranding," where nail became stuck in plaintiff's leg); *Toole v. Richardson-Merrell, Inc.*, 251 Cal.App.2d 689 (1967) (company filed NDA, reporting 50% death rates in animal testing when 100% had died, and included wholly fictitious data).

Our review of the statutes and regulations admitted here raises questions on whether they can be used to establish a standard of care for negligence *per se* purposes in the absence of adequate examination by the trial court to determine whether they were applicable and whether they could be understood by the jury without guidance from the court or expert testimony concerning their meaning. The court admitted dozens of statutes and regulations, some possibly applicable in the determination of a standard of care and at least one clearly not. For example, while McNeil does not contest that the FD&C Act and FDA regulations are safety statutes, we agree with its contention that the criminal statute prohibiting false statements to the government, 18 U.S.C. § 1001 (1958), which was also admitted by the trial court, was not intended to promote public safety and has no bearing on the issues presented here. *See Hubbard v. United States*, 115 S. Ct. 1754, 1761 (1995) (18 U.S.C. § 1001 "was passed at the behest of 'the Secretary of the Interior to aid the enforcement of laws relating to . . . transportation of hot oil' "). Hawkins made no attempt to justify the use of 18 U.S.C. § 1001, or 15 U.S.C.A. § 51-57 (1973 & 1993 Supp.)

(prohibiting false advertisements), as applicable under negligence *per se* principles.

We have implied in prior holdings that many complex or technical statutes, such as those at issue here, may not be used for negligence *per se* purposes without expert testimony or guidance from the court to assist the jury's understanding. *See, e.g., Lewis, supra* note 21, 463 A.2d at 674. In that regard we note that in reviewing these cases where the negligence *per se* principle was accepted, the general subject matter of the cases involve principles familiar to lay jurors' everyday lives. For example, it can hardly be said that any juror would be confused by a statute requiring a home to be "in repair," *see Whetzel v. Jess Fisher Management Co.*, 108 U.S. App. D.C. 385, 392, 282 F.2d 943, 950 (1960) (housing code violation allegedly caused falling ceiling to injure tenant), or one requiring a temporary cover of a floor opening at a construction site to be "securely fastened in place" to withstand reasonable weight or shock. *See H.R.H. Constr. Co. v. Conroy*, 134 U.S. App. D.C. 7, 411 F.2d 722 (1969) (safety code violated by temporary cover over air-conditioning duct; worker injured when he stepped on loose board covering duct that was three inches smaller than opening itself); *see also Elliott v. Michael James, Inc.*, 182 U.S. App. D.C. 138, 559 F.2d 759 (1977) (building code violated where doors were unlawfully locked on inside; restaurant employee unable to escape assailant and was fatally stabbed). Most adults are familiar with automobiles and the rules of driving, therefore, experts are not needed to explain the meaning of statutes and regulations governing such everyday experiences. *See Ross v. Hartman*, 78 U.S. App. D.C. 217, 139 F.2d 14 (1943) (violation of ordinance requiring motor

vehicles to be locked was negligence *per se* in action by party injured by the stolen vehicle); *see also Bauman v. Sragow*, 308 A.2d 243, 244 (D.C. 1973) (traffic regulations); *District of Columbia v. Nordstrom*, 117 U.S. App. D.C. 165, 327 F.2d 863 (1963) (traffic regulation prohibiting parking of vehicles on sidewalk could be submitted as applicable standard of care where pedestrian was injured trying to avoid the unlawfully parked vehicle). Similarly, jurors are generally familiar with how drinks are sold in a tavern, *see Zhou, supra*, 534 A.2d 1268 (Alcohol Beverage Control Act), and can understand the danger of lighting a match in an area "heavily permeated with the smell of gas fumes." *Gaither v. District of Columbia*, 333 A.2d 57, 60 (D.C. 1975) (D.C. Code 1973, § 24-442). The same cannot be said of the statutes and regulations admitted in this case.

Before admitting statutes and regulations offered for negligence *per se* purposes, a trial judge must examine each law to determine first, whether it in fact established a standard of care, and if so, whether it could be reasonably understood by the jury without expert testimony or guidance by the court.[22] *See Lewis, supra*, 463 A.2d at 674;

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[22] Although we do not reach the question whether it was appropriate for the trial court to submit copies of the statutes and annotations to the jury, we note that other courts have found that practice to be improper. *See Domijan v. Harp*, 340 S.W.2d 728, 734 (Mo. 1960) (introduction into evidence of domestic statutes (or law) is wholly improper for damage calculations); *Saffold v. McGraw-Edison Co.*, 566 F.2d 621, 623 (8th Cir. 1977) (in products liability action, "the proper procedure would have been for the trial court to judicially notice the statutes, instruct the jury as to their applicability and prohibit the reading of the statutes or reference to their criminal aspects").

see also Bammerlin v. Navistar Int'l Transp. Corp., 30 F.3d 898, 900 (7th Cir. 1994) (trial judge made "serious mistake" by leaving jury to interpret meaning of ambiguous motor vehicle safety standards). Particularly instructive on this point is *Lewis*, where the owners of a building sued a subway construction company, alleging the company negligently failed to maintain adequate support for the building during the subway excavation. The trial court admitted into evidence two provisions of the building code as evidence of negligence, but, citing its doubt about the regulations' applicability to the case, refused the owners' request for a negligence *per se* instruction. On appeal, we concluded that the trial court did not err in declining the negligence *per se* instruction. We noted the failure of the plaintiff-owners to "proffer any evidence regarding the purpose and scope of the two building code sections or the meaning of the key terms in them." *Lewis, supra*, 463 A.2d at 674. We also noted that the owners failed to make a threshold showing that the statutes were applicable and presented insufficient evidence that the regulations were, in fact, violated. *Id. See also Hecht Co. v. McLaughlin*, 93 U.S. App. D.C. 382, 385, 214 F.2d 212, 215 (1954) (court should consider proffered expert testimony on the admissibility question where the scope of the statute is unclear); *Northern Trust Co. v. Upjohn Co.*, 572 N.E.2d 1030, 1040 (1991) (Ill. App. Ct. 1991) (FD&C Act misbranding statute that required listing of side effects was admitted for jury consideration; whether defendant was obligated to include cardiac arrest as a possible side effect on drug label was a complex question which required expert testimony).

For the reasons stated, we conclude that the trial court erred by not conducting an inquiry into whether *each* statute and regulation was appropriate to serve as an intelligible standard of care for negligence *per se* purposes.[23] That error would not, by itself, require reversal, however, if, upon our own examination, we concluded that the statutes and regulations were properly admitted without the need for further guidance by the trial court or expert testimony. We need not make that determination in this case because we conclude, for the reasons stated below, that the judgment must be reversed for another reason. Even though the statutes in question should not have been admitted as exclusive proof of the standard of

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[23] Alaska state courts have established a two-step inquiry for trial courts to follow when asked to instruct a jury that violation of a statute or ordinance establishes negligence as a matter of law. *See State Mechanical, Inc. v. Liquid Air, Inc.*, 665 P.2d 15, 18-19 (Alaska 1983); *see also Sinclair v. Okata*, 874 F. Supp. 1051, 1062-63 (D. Alaska 1994) (adopted A.M.C. § 17.10.020(A) (1986) as standard of care for dog and cat owners; statute provides that "[a] person who owns a dog or a cat shall keep that animal under restraint at all times"); *Ferrell v. Baxter*, 484 P.2d 250, 264-65 (Alaska 1971). First, the court applies the four criteria outlined in the Restatement (Second) of Torts § 286, to determine whether the statute or ordinance was designed to cover the conduct in question. If the court decides the first inquiry in the affirmative, it then considers whether the rule of law is so obscure, outdated, or arbitrary as to make inequitable its adoption as a standard of reasonable care. *Id.*

If the Alaskan court declines, for either reason, to instruct the jury that a violation of the statute establishes negligence *per se*, it may, in its discretion, either admit the statute or ordinance as evidence of negligence or it may exclude reference to the statute altogether. *Sinclair, supra*, 874 F. Supp. at 1062.

care for the reasons stated, without more careful screening by the trial judge, the statutes nonetheless were admitted and were available to the jury to consider either as establishing or as evidence of the standard of care. *See Zhou, supra,* 534 A.2d at 1274 (statutory violation may be admitted as evidence of negligence even though the court does not find it appropriate for negligence *per se*) (citations omitted). We now turn to our analysis of whether Hawkins established a breach of the standard of care.

C. Proof of breach of standard of care

McNeil further contends that, at the very least, the jury should have been guided, either by the trial court or through expert testimony, in its application of the statutes. Where the statutes and regulations are admitted as the basis for a finding of negligence *per se*, or as evidence of negligence, the plaintiff must also prove a deviation from the standard of care, *i.e.*, that the statutes were in fact violated. *See, e.g., Zhou, supra,* 534 A.2d at 1277 (jury "must surmount the threshold question" of whether, in fact, the statute has been violated); *Stevens v. Hall,* 391 A.2d 792, 796 n.2 (D.C. 1978) (even where *per se* rule is applicable, "jury may have a difficult threshold question as to whether, in fact, the relevant statute or regulation has been violated").[24]

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[24] "In addition, plaintiffs must prove that the statutory violation was the proximate cause of their injuries." *Zhou, supra,* 534 A.2d at 1277. Although McNeil claims such proof was lacking here, we need not address that issue.

The trier of fact is sometimes confronted with issues that require scientific or specialized knowledge or experience in order to be properly understood, and which cannot be determined intelligently merely from the deductions made and inferences drawn on the basis of ordinary knowledge, common sense, and practical experience gained in the ordinary affairs of life. *See District of Columbia v. Hampton*, 666 A.2d 30, 35 (D.C. 1995); *Payne, supra*, 486 A.2d at 727 & n.17; *see also* 31A AM. JUR. 2D, *Expert and Opinion Evidence* § 5 (1989). On such issues, the general rule in the District of Columbia is that testimony of one possessing special knowledge or skill is required in order to arrive at an intelligent conclusion. *Hampton, supra*, 666 A.2d at 35 (referring to professional medical malpractice cases). In a "substantially smaller number of cases," however, the plaintiff is not required to adduce expert testimony to establish the applicable standard of care where "negligent conduct is alleged in a context which is within the realm of common knowledge and everyday experience." *Id.*; *Beard v. Goodyear Tire & Rubber Co.*, 587 A.2d 195, 200 (D.C. 1991) (citations omitted); *see also White, supra*, 442 A.2d at 164 (expert testimony to prove a deviation from the proper standard of care is required "when the subject presented is 'so distinctly related to some science, profession, business or occupation as to be beyond the ken of the average layman' ") (quoting *Hughes v. District of Columbia*, 425 A.2d 1299, 1303 (D.C. 1981)). In *Hampton*, this court noted that "[t]he general rule is most commonly applied . . . in professional malpractice cases . . . [but] the requirement has been applied more broadly in a variety of situations." *Hampton, supra*, 666 A.2d at 35 (citations omitted). Thus, had

Hawkins presented proof of the standard of care, and its breach, through traditional negligence analysis, she would most certainly have been required to present that proof through expert testimony.

In addition, this jurisdiction has required expert testimony to explain the applicability of statutes where the statute is relied upon as establishing the standard of care. In *Hecht Co. v. McLaughlin, supra,* 93 U.S. App. D.C. at 382, 214 F.2d at 212, where the plaintiff was injured by a "modern" door, "not the ordinary type," on the defendant department store's property, the trial court instructed the jury that the violation of a building code regulation would be negligence as a matter of law, but rejected the testimony of a liaison officer of the District of Columbia Building Department that the regulation did not apply to the situation before the court. The United States Court of Appeals for the District of Columbia Circuit, in an opinion binding on us,[25] reversed, noting that the installation of the door had been approved by the Department of Building Inspection, and holding that the trial court's "failure to receive expert testimony as to the interpretation, and consequent admissibility and application, of the regulation, and the instruction that its violation would constitute negligence *per se* require[d] reversal."[26] *Id.*, 93 U.S.App. D.C. at 386, 214 F.2d at 216. In so holding, the court cited *Wright v. Wardman,* 55 App. D.C. 318, 319, 5 F.2d 380, 381 (1925) (dubiously worded

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[25] *See M.A.P. v. Ryan,* 285 A.2d 310 (D.C. 1971).

[26] In the present case, Hawkins did not offer any such testimony.

zoning regulation) which held that where there is uncertainty about the meaning of a "statute, ordinance, or regulation," the expert or administrative view will generally control its interpretation. *Wright, supra,* 55 U.S. App. D.C. at 319, 5 F.2d at 381.

In this case, for the reasons stated below, in the face of defense experts who testified that there was no breach of the standard of care, and statutes and regulations which required expert explication, we hold that Hawkins was required to present expert testimony concerning the interpretation of the statutes and regulations relied upon by her, so that the jury would be guided in its application of those sources to the conduct at issue in this case. The jury then would have been able to determine whether McNeil deviated from the proper standard of care, *i.e.*, whether McNeil's conduct violated the statutes and regulations.[27]

We are persuaded to that view by the well-reasoned opinion of the court in *Northern Trust Co. v. Upjohn Co.*, 572 N.E.2d 1030, 1040 (Ill. App. Ct. 1991), *cert. denied*, 502

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[27] Other jurisdictions have indicated that expert testimony should be considered to determine whether a warning is adequate in non-negligent *per se* situations. In *Graham v. Wyeth Laboratories*, 666 F. Supp. 1483 (D. Kan. 1977) (not a negligence *per se* case), the court stated, "It is well established in Kansas that whether a warning is adequate is an issue for the trier of fact. Moreover, the testimony of experts in the field should be considered." *Id.* at 1499 (internal citations omitted); *see also Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 841-42 (Ohio 1981) (expert witness could respond to hypothetical question whether defendant doctor "deviated in any way from the acceptable standards of practice").

U.S. 1095 (1992). In that case, the plaintiff suffered a cardiac arrest and sustained brain injury after a doctor administered the drug Prostiglandin F2 Alpha ("Prostin"), manufactured by the Upjohn Company. Northern Trust Company, as guardian of plaintiff's estate, sued Upjohn for negligent failure to warn and for product liability, contending that although Upjohn was aware of at least nine instances where cardiac arrest and/or death occurred after Prostin was administered, the label on the drug did not list cardiac arrest as a possible side effect. The jury was instructed that it could consider whether Upjohn violated any statute, regulation, or ordinance in deciding whether it was negligent and/or manufactured an unreasonably dangerous product.[28] The jury returned a verdict for the plaintiff for over $9 million.[29] On appeal, however, the Appellate Court of Illinois reversed the judgment.

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[28] The statutes and regulations involved in *Upjohn* were similar to those presented in this case, although considerably fewer in number. The trial court in *Upjohn* quoted in pertinent part the following statute and regulations in its instruction to the jury: 21 U.S.C. § 352(a), (f), (j), and (n) ("Misbranded drugs and devices"; drug misbranded if its labeling was found to be false or misleading); 21 C.F.R. §§ 1.3(a)(1), (2); 314.8(a), (b), (d), (e) and (l) (labeling of drug misleading if it failed to reveal facts that were "material in light of other representations made;" changes in labeling, advertising or warnings concerning a drug's side effects should be "placed into effect at the earliest possible time.") *Upjohn, supra*, 572 N.E.2d at 1036-37.

[29] The verdict was against all defendants, Upjohn, the administering doctor and the hospital, jointly and severally.

The *Upjohn* court first held that, "by logical extension" to the requirement of expert testimony in medical malpractice cases, "expert testimony shall be necessary and proper in a case, . . . where a drug manufacturer's liability for a prescription drug is based upon its failure to provide adequate warnings," except where the inadequacy of the warning is so obvious that a lay person could understand its insufficiency. *Id.*, at 1036. The court then went on to address whether, under the facts presented to it, expert testimony was required.

The court ultimately concluded that expert testimony was required to establish both (1) the "complex question" of Upjohn's duty to warn of reported cases of cardiac arrest, *i.e.*, that knowledge of those cases was tantamount to knowledge of an "association" between the drug and cardiac arrest,[30] and (2) that Upjohn abrogated its duty, *i.e.*, that the label was inadequate to warn physicians of the potential dangers inherent in the use of the drug. *Id.* at 1037-38. In so holding, the court reasoned that "it seems clear that the meaning and medical implications of several of the listed adverse reactions is outside the knowledge of the ordinary lay person," *id.* at 1039, and a lay person "would be unable to determine, for example, whether a drug was "misbranded" [as defined by the statute] unless expert testimony was provided."[31] *Id.* at 1040.

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[30] The court concluded that "the link between Prostin and cardiac arrest was not so apparent that expert testimony was not necessary to establish that a duty was imposed upon Upjohn to include cardiac arrest in the warnings." *Upjohn, supra*, 572 N.E.2d at 1038.

[31] "The typical juror would be unqualified to determine, without the aid of expert testimony, whether the failure to

In this case the trial court admitted dozens of statutes and regulations. Our examination satisfies us that, with three possible exceptions, all involve use of generalized language which would require expert testimony to explain to jurors how McNeil violated them. One of the remaining three, 18 U.S.C. § 1001, is clearly not applicable, as we said earlier. The last two statutes at first seem capable of lay application. However, though parts of 15 U.S.C.A. §§ 51-57 (1973 & 1993 Supp.) (prohibiting false advertisements) seem straightforward, the definitional section, § 55, is quite intricate and may involve complicated implementing regulations. Likewise, 21 U.S.C. § 352 (1958) appears straightforward on its face. But lay jurors may not understand, since it is not apparent on the face of the statute, that the statute is supplemented in great detail by the regulations of 21 C.F.R. §§ 201.1-201.316 (1990). Although these regulations were submitted to the jury, lay jurors would be unable to assess how the regulations affect interpretation of the statute without expert testimony to help them apply the appropriate standard of care.

A review of the testimony in this case reveals that Hawkins presented no competent expert testimony regarding the violation of the statutes and regulations submitted to the jury. While Hawkins attempted to elicit testimony regarding violations of the regulations from its "expert" witnesses, she was not allowed to do so because

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include "cardiac arrest" was a "material misrepresentation," as defined by the statute, which made the warnings false, misleading or inadequate to direct the drug's usage." *Id.* at 1040.

her medical experts lacked expertise in assessing submissions to the FDA, and they were not allowed to answer questions incorporating the terms of the regulatory requirements. In contrast, McNeil's experts were qualified to testify that McNeil's labeling was fully adequate to inform physicians about the risks and benefits of the drug, that McNeil was at all times in compliance with FDA regulations regarding chlorzoxazone, and that its labeling for the product was fully adequate. They also testified that there was no need to include rechallenge information in the label for chlorzoxazone, and that there is no regulatory requirement that positive rechallenges be described in drug labeling.

Hawkins maintains that she presented numerous expert witnesses to establish that McNeil's labeling was inadequate, and thus, that McNeil violated the standard of care. In particular, Hawkins cites the testimony of Dr. Golombos, qualified as an expert in the disease of the liver, who testified, *inter alia*, that based on his review of the NDA and the clinical records of Dr. Drew, all significant information necessary to determine the safety of the drug was not submitted by McNeil to the FDA. The trial court, however, precluded Dr. Golombos from testifying whether the information allegedly withheld by McNeil from the FDA would affect the FDA's approval or constitute a violation of the statutes. Dr. Golombos had not been qualified to opine whether McNeil had breached its statutory or regulatory responsibilities. The trial court explained:

> Why was he [Dr. Golombos] foreclosed from testifying about the Food and Drug Administration [a]nd their requirements? [B]ecause each

> time that the preliminary foundational question of knowledge came up, he was lacking in it, never having worked for the FDA and been in a position to assess, evaluate and pass on the Food and Drug Administration standards.

The expert testimony presented by Hawkins may have been sufficient had Hawkins presented traditional evidence of the standard of care,[32] where the label must merely be proven to be unreasonable under the circumstances. *See, e.g., Payne, supra,* 486 A.2d at 722 n.10 (in negligent failure to warn case, absence of proper warning can range from complete absence of any warning to warning which is given but is inadequate; test of propriety has been expressed as whether the warnings given are "reasonable under the circumstances"). In this case, however, the only evidence of a standard of care offered by Hawkins was that embodied in the statutes and regulations. Therefore, in order to prove her case, it was incumbent on Hawkins to prove a violation of those statutes and regulations. And, in order to do that, Hawkins was required to present an expert who was familiar with the application of the statutes and regulations. *See Snead v. United States,* 595 F. Supp. 658, 663 (D.D.C. 1984) (to give opinion on whether defendant physician complied with applicable standard of care, witness physician must be

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[32] This is also true of Hawkins's argument that whether a violation occurred is a question of fact for the jury. As we have explained above, the statutes and regulations were not within the realm of common knowledge, therefore, the jury needed guidance from someone with special knowledge of their application.

familiar with that standard).[33] She did not do so, therefore she did not present to the jury any evidence that McNeil violated the only standard of care offered, *i.e.*, the statutes and regulations.

IV. Conclusion

We reverse on the negligence *per se* claim because Hawkins did not present sufficient evidence of the standard of care, or that any such standard had been violated. We also hold that because Hawkins failed to adequately establish a standard of care or a deviation from that standard, she also failed to satisfy the element of proof under § 402A of the Restatement (Second) of Torts, or a "defective condition unreasonably dangerous," required for her strict liability claim. *See Warner Fruehauf Trailer Co. v. Boston*, 654 A.2d 1272, 1276 (D.C. 1995) (plaintiff must establish that defendant sold product in question in a "defective and unreasonably dangerous condition"). Accordingly, judgment as a matter of law should have been entered in favor of McNeil on both Hawkins's negligence *per se* and strict liability claims.[34]

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[33] *See Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1112-13 (5th Cir. 1991) (fact that expert has a medical degree does not qualify him to give opinion on every conceivable medical question).

[34] McNeil contended that Hawkins failed to show a causal connection between the alleged violations and the injury. Specifically, McNeil argued that Dr. Burgerman, who prescribed the drug to the deceased, testified that he did not read or rely on the allegedly inadequate label, and there was no testimony as to how Dr. Burgerman would have acted had he read the label. In *Mampe v. Ayerst Laboratories*, 548 A.2d 798 (D.C. 1988), on facts

For all of these reasons the judgments in favor of Hawkins must be reversed and remanded with instructions to enter judgment for McNeil.

Reversed.

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similar to the present case, we held that proximate cause had not been proven where there was unrebutted evidence that, regardless of whether the doctor read the allegedly inadequate warning label, the information contained in the label would have had no effect on his decision to prescribe the drug. *Id.* at 802. Because we resolve this case on other grounds, we do not address the issue of proximate causation.

APPENDIX B

DISTRICT OF COLUMBIA COURT OF APPEALS

Nos. 94-CV-1346 and 94-CV-1396

McNEIL PHARMACEUTICAL,

Appellant/cross-appellee,

v. CA10680-90

DELORES HAWKINS,

Appellee/cross-appellant.

BEFORE: *Wagner, Chief Judge; Ferren, Terry, *Steadman, Schwelb, Farrell, *King, Ruiz, and Reid, Associate Judges.

ORDER
(Filed Apr. 21, 1997)

On consideration of the petition of appellee/cross-appellant for rehearing en banc, the motion of Trial Lawyers Association of Metropolitan Washington, DC, for leave to file amicus curiae brief in support of petition, the lodged brief, and the response of appellant/cross-appellee to the petition and the brief, it is

ORDERED that the motion of Trial Lawyers Association of Metropolitan Washington, DC, is granted and the Clerk is directed to file the lodged brief of amicus curiae; and it appearing that the majority of the judges of this court has voted to deny the petition for rehearing en banc, it is

FURTHER ORDERED that the petition for rehearing en banc is denied.

PER CURIAM

Associate Judges Ferren and Reid would grant the petition for rehearing en banc.

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APPENDIX C

DISTRICT OF COLUMBIA COURT OF APPEALS

Nos. 94-CV-1346 & 94-CV-1396

McNEIL PHARMACEUTICAL,
Appellant/Cross-Appellee,

v.

DELORES HAWKINS,
Appellee/Cross-Appellant.

PETITION FOR REHEARING *EN BANC*

Pursuant to Rule 40, appellee/cross-appellant Delores Hawkins respectfully petitions for rehearing *en banc*. On December 23, 1996, a division of this Court issued a startling opinion, declaring that the law of the District of Columbia does not recognize strict liability as a distinct theory of liability for a drug manufacturer who sold a misbranded drug with inadequate warnings and caused the death of a woman through drug-induced liver failure. The division's novel view of tort law is at odds with well-established precedent.[1] Moreover, the adoption of this new rule of law by a division of the Court is contrary to the established rule in the District that an

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[1] *See, e.g., Berman v. Watergate West*, 391 A.2d 1351 (D.C. 1978); *East Penn Mfg. Co. v. Pineda*, 578 A.2d 1113 (D.C. 1990); *Payne v. Soft Sheen Products, Inc.* 486 A.2d 712 (D.C. 1985); *Warner Fruehauf Trailer Co., Inc. v. Boston*, 654 A.2d 1272, 1277 (D.C. 1995).

extension or revision of the law must be made by either the legislature or the Court *en banc*.[2]

The division held as a matter of law that misbranding and inadequate warnings are not enough to impose liability on McNeil Pharmaceutical ("McNeil"). Instead, the division held that the seller of a misbranded drug with inadequate warnings may only be held liable if it engaged in negligent conduct. Notwithstanding the jury's finding in this case that McNeil had willfully sold a defective and misbranded product with inadequate warnings, in reckless disregard of the safety of consumers,[3] the division held that such a verdict could not stand because the plaintiff relied solely on McNeil's willful violation of the Federal Food, Drug & Cosmetic Act ("the Act"),[4] to establish the standard of care. In the division's view, Mrs. Hawkins could not prove breach of the Act by showing through expert testimony the intentional withholding of

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[2] *See Gray v. Citizens Bank of Washington*, 602 A.2d 1096 (1992) (division is not free to expand exception to at will doctrine); *Gray v. Citizens Bank of Washington*, 609 A.2d 1143 (1992) *(en banc)* (dismissing petition as improvidently granted; but see dissent by Wagner, J.); *Asuncion v. Columbia Hospital for Women*, 514 A.2d 1187, 1189 (1986) (division not at liberty to expand law on negligent infliction of emotional distress).

[3] In its response to interrogatory No. 2, the jury specifically found defendant's labeling to be inadequate and misleading. Tr. 666. Moreover, in response to Interrogatory No. 4, the jury found that McNeil acted or failed to act willfully or out of a reckless disregard for the rights of individuals. Tr. 666.

[4] Food, Drug, and Cosmetics Act, as amended, 21 U.S.C. §§ 301-321, *et seq.* (1982). 21 U.S.C.§ 352 provides that a drug is misbranded "if its labeling is false or misleading in any particular."

material information about the drug's dangers; instead, she was required to introduce an expert's opinion that the defendant's intentional concealment and falsification of material information on the drug's danger violated the Act.[5] Consequently, the division determined as a matter of law that the jury could not hold the manufacturer responsible for Mrs. Gilliam's death. In effect, the division's opinion held that the jury was incompetent to determine whether the drug's labeling was false and misleading.

If allowed to stand, this opinion will have a profound effect not only on the immediate parties to the litigation, but also on the law that governs the sale of defective products in the District, and could jeopardize the public safety that product liability law was designed to promote.

First, the division adopted new tort law that effectively eliminates strict product liability as a separate cause of action in cases involving inadequate warnings of product danger. Second, the division ruled that the filing requirements of the Act are too complex for a jury to rely on in order to determine a drug company's standard of care in the absence of expert testimony.[6] Once again, the

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[5] *See* slip op., at 25, 31.

[6] Courts have consistently held that there is nothing indefinite or ambiguous in 21 U.S.C. § 352(a). *United States v. 62 Packages More of Less of Marmola Prescription Tablets*, 48 F.Supp. 878 (D. Wisc. 1943), *aff'd*,142 F.2d 107, *cert. denied*, 323 U.S. 731 (1944). Indeed, criminal convictions have been upheld by the U.S. Supreme Court for violations of the Act and its implementing regulations on the basis of strict liability. *United States v. Park*, 421 U.S. 658 (1975); *United States v. Dotterweich*, 320 U.S. 277 (1943).

division interpreted the law in a way that clashed with well-established precedent.[7] The division embraced this novel view of the Act even though the provisions of the Act relied on in the present case are plain in meaning and experts presented testimony explaining the medical significance of the information that McNeil either willfully failed to report to the Food & Drug Administration or deliberately falsified.[8] Moreover, its action leaves in its

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[7] *Stanton by Brooks v. Astra Pharm. Prod., Inc.*, 718 F.2d 553 (3d Cir. 1983); *Toole v. Richardson-Merrill, Inc.*, 251 Ca. App.2d 689 (1967).

[8] McNeil's expert, Dr. Goddard, a former head of the FDA, provided expert testimony on direct and cross examination as to the meaning and purpose of the Act. Tr. 6/16/93, pp. 19-30; Tr. 6/17/93, pp. 63-80.

Plaintiff's expert, Dr. Galambos, a Board-certified gastroenterologist, was asked by the court: "Having practiced medicine, understanding the workings of the liver, under those factors that a physician must consider before prescribing to a patient, do you believe that the information made available of Parafon Forte DSC was sufficient to a reasonable degree of medical certainty to allow a physician to make a considered judgment of how and when to prescribe this medication?" He answered: "My position is that physicians had misleading information . . . . The basis of my opinion is that this drug as I have seen, the data, clearly can cause hepatitis. The information given to us physicians on this drug through the years reassured us that this drug probably or may or may not cause hepatitis, but there are always other explanations . . . and this is the kind of information that as a doctor who has a patient on this drug either would be alert and considered the possibility of drug induced hepatitis or I would be reassured and wouldn't' be very alert in looking for it" (Tr. 6/1-2/93, p. 155-157).

For further more specific testimony from Dr. Galambos regarding McNeil's conscious provision of misleading information and the inadequacy of the warning, *see* Tr. 6/1-2/93

wake substantial confusion regarding the criteria to be used in setting requirements for expert testimony.

Third, in light of its precedent-setting, novel analysis of strict liability law and evidentiary requirements, the division should have, at most, remanded for a new trial. Instead, the division took the extraordinary step of mandating a verdict for McNeil. In doing so, **it effectively substituted its view of the appropriate outcome of the litigation for that of the jury,** thus reading the evidence in the light most favorable to the verdict *loser*, the drug manufacturer.[9] This violated long-standing practices of

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at pp. 31-159. *See, particularly,* pages 73-74 where Dr. Galambos described the effect of the absence of the Batterman, Drew and Peak results: "My opinion is that it does have an effect in two ways. One in the decision whether or not to use this drug or an alternate drug, but more importantly once this drug is used, what's the degree of suspicion in evaluating your patient's symptoms if and when side effect developed that suggest liver injury."

[9] Moreover, the division's conclusion that a new trial was unjustified rests on troublesome reasoning. Mrs. Hawkins proffered expert testimony on standard of care. Despite sound argument from the plaintiff supporting admissibility of the proffered testimony, the trial judge rejected it. Mrs. Hawkins did not challenge the rulings of the trial court as a principal error in her briefs since she had won the verdict despite the trial court's erroneous rulings. By its ruling, the division has deprived the plaintiff of the opportunity to present her claims; instead, the division remanded the case to the trial court with directions to enter judgment for McNeil. The effect is to penalize the verdict winner for not raising and preserving every objection to every error made by the trial court, even though those errors only become relevant if the appellate court reverses the decision below.

appellate review. Each of these departures from well-established legal principles necessitates rehearing *en banc*.

1. Contrary to the division's erroneous assertion, the plaintiff did *not* rely solely on breach of statute to prove McNeil's breach of duty. Mrs. Hawkins alleged, and proved to the satisfaction of the jury and the trial judge, that McNeil was responsible for the death of her mother, Elva Mae Gilliam, under theories of common law negligence, negligence *per se*, strict product liability and common law fraud.[10] Based on the testimony of distinguished medical experts[11] during a month-long trial, a jury found that McNeil intentionally withheld from both the medical community and the FDA information establishing that its prescription drug, Parafon Forte DSC, which McNeil marketed as a muscle relaxant, posed a significant risk of causing the consumer life-threatening liver damage.[12] Despite the jury's findings (1) that the drug was misbranded and sold with an inadequate warning; (2) that Mrs. Gilliam died as a result of liver damage caused by Parafon Forte; (3) that McNeil had intentionally violated the Act;[13] and (4) that McNeil had

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[10] Tr. 665, *et seq.* Each of these theories were submitted to the jury.

[11] Plaintiff's experts, Drs. Patrick Joseph Dean, John Galambos and Bernard Powers, were qualified as experts in their areas of expertise, as set forth in the Court's opinion at pp. 12-15. Dr. Galambos was a past president of the American College of Gastroenterology.

[12] 21 U.S.C. § 352(a); 21 U.S.C. § 355(j); 21 U.S.C.§ 331(a) (b) & (e), and their implementing regulations. *See* slip op., at 10-11.

[13] Numerous courts interpreting 21 U.S.C. § 352(a) have held that one false statement in a drug's labeling can render a

engaged in reckless conduct, the division concluded that McNeil should prevail as a matter of law.

By treating the multiple claims before the jury as though they amounted to a single claim of negligence through statutory violation, the opinion issued in this case represents a radical departure from established product liability law in the District and undermines the basic aims of product liability law to place the risk of injury from defective products on the product manufacturers. The opinion misapprehends a fundamental principle of tort law: a claim of negligence focuses on *conduct* while a claim of strict liability focuses on the *condition* of a product.[14] The division's holding that an inadequate warning claim requires the same proof whether plaintiff asserts a strict liability or negligence theory (*see* slip op., at 21.) is troublesome in light of precedent and policy.

The Supreme Court of California considered the same issue in 1996 in a case involving a prescription drug, and concluded in a thoughtful and enlightening opinion by Justice Mosk that strict liability remains a distinct theory for a strict liability claim based on an inadequate warning.[15] Plaintiff urges the court to review

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drug misbranded. *United States v. 6 Dozen Bottles*, 158 F. 2d 667 (7th Cir. 1947); *United States v. Diapulse Manufacturing Corp.*, 269 F.Supp. 162 (D.Conn. 1967).

[14] *See, e.g., Warner Fruehauf Trailer Co., Inc., supra; O'Brien v. Musker*, § 463 A.2d 298, 303 (N.J. 1983); *Carter v. Johns-Manville Sales Corp.*, 557 F.Supp. 1317, 1318 (E.D. Tex. 1983).

[15] *Carlin v. The Superior Court of Sutter County; The Upjohn Company, Real Party In Interest*, 13 Cal.4th 1104, 56 Cal.Rptr.2d 162, 920 P.2d 1347 (1996).

the *Carlin* decision and carefully consider *en banc* whether the division's view in this case should be adopted as the new rule in the District.

It is beyond dispute that the District has to date recognized the distinct strict liability action based on inadequate warnings.[16] The division's opinion in the present case reveals a failure to appreciate the subtle but important distinction between strict liability and negligence in an inadequate warning claim related to an unavoidably dangerous product such as a drug. In this context, a strict liability claim overlaps with a negligence claim to the extent that some degree of foreseeability of risk is necessary for both claims.[17] It is the shared requirement of foreseeability in many jurisdictions which has prompted some courts and commentators to assert that negligence and strict liability claims are effectively the same when the claim is based on inadequate warnings.[18] This, however, does not mean that "negligence and strict liability, in failure to warn cases, are, in the

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[16] *East Penn Mfg. Co., supra; Payne, supra; Russell v. G.A.F. Corp.*, 422 A.2d 989 (D.C. 1980).

[17] *See* the discussion of foreseeability in the California Supreme Court in *Carlin, supra*, n.14.

[18] *See Carlin, supra*, n. 15, 920 P.2d at 1350, quoting *Anderson*, 53 Cal.3d at 1002-1003. "Failure to warn in strict liability differs markedly from failure to warn in the negligence context. Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor . . . fell below the standard of care. . . . Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct. The rules of strict liability require a plaintiff to prove only that the defendant did not adequately warn of a particular risk that was known or knowable. . . . "

division's words, "functional equivalents."[19] What the opinion ignores is that once a risk is characterized as foreseeable, a strict product liability claim shifts its focus to the defective condition of the product as sold; in contrast, a negligence claim focuses on the reasonableness of the seller's conduct.[20] Significantly, a seller of a product that is defective due to inadequate warnings can be held strictly liable for harm caused by the *defective product*, even though it exercised reasonable care in designing, manufacturing and marketing the product. The critical question is whether the product as sold was defective due to misbranding and the inadequate warning.[21] To be exempt from strict liability, consequently, requires that the seller of an unavoidably dangerous product such as a drug, both properly prepare and market the drug and adequately warn about its risks.[22] If proper warning is not given, the seller is strictly liable, regardless of whether it violated a standard of care.[23]

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[19] *See* slip op., at 20.

[20] *See* discussion in *Carlin, supra*, n.1, 920 P.2d at 1350-1351, and *Warner Fruehauf Trailer Co., supra*, n. 1, 654 A.2d at 1277.

[21] *See Warner Fruehauf Trailer Co., supra*, n. 1.

[22] Comment k of Section 402A of the *Restatement (Second) of Torts* expressly provides with respect to unavoidably dangerous products: "The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it is not to be held to strict liability. . . . "

[23] In the words of Section 402A,(2)(a), strict liability applies although "the seller has exercised all possible care in the preparation and sale of his product."

A careful analysis of strict liability and negligence doctrines discloses that even if the doctrines seem to merge in some cases as to the way each handles the issue of foreseeability, this merger is an irrelevant concern in the present case. This was *not* a case where a manufacturer acknowledged a risk posed by a product but contended that the risk was unforeseeable at the time the product was sold. The contested issues at trial in this case did not involve foreseeability, but rather whether the drug in fact posed a risk of liver damage and, if it did, whether the risk was significant enough to require a warning.[24]

2. The entire Court should review this case to clarify whether the Act may be relied on in a tort case to establish the standard of care, thereby effectively performing the same function that an expert would serve. Prior to the division's decision in this case, the law was well-established in this jurisdiction and others that a court may adopt a criminal statute to define the standard of care in a tort case by applying the criteria set forth in Section 286 of the *Restatement (Second) of Torts*. In the face of numerous cases that have adopted the provisions of

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[24] To the extent that foreseeability is implicated, the jury's verdict reveals its finding that the risk of liver damage caused by Parafon Forte was known to McNeil. The trial judge excluded evidence that this drug's parent drug, zoxazolamine, was removed from the market by the FDA in 1961 because it caused liver damage. Additional issues involved how much McNeil knew about that drug's risk of causing liver damage, and whether it had been honest with the FDA and the medical community concerning its knowledge. On those issues both parties offered numerous expert witness and numerous documents.

the Act in a tort case against a drug manufacturer,[25] the division chose to rely on an inapposite decision interpreting Illinois law.[26]

In addition, the division has ruled that some of the provisions of the Act are too complex to apply in a tort case and others are inappropriate for use. It failed, however, to delineate clear criteria by which trial courts may determine when expert testimony is required and what kind of expert must be provided. In this case, the statutory provisions appear simple and straightforward; they unambiguously require submission of all material information regarding the risks associated with the use of a drug. Moreover, to the extent that the jury needed specific expert testimony to understand the Act, they were provided that testimony through cross-examination of defendant's expert, Dr. Goddard, a former FDA employee. Dr. Goddard admitted that the failure to report material information or to supply full and complete information about the risk of liver damage to the FDA would violate the Act.[27] The division's implicit conclusion that

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[25] *See* n. 6, *supra*.

[26] *See* slip op., at 31-33, relying on *Northern Trust Co. v. Upjohn Co.*, 472 N.W. 2d 1030, 1040 (Ill.App.Ct. 1991), *cert. denied*, 502 U.S. 1095 (1992).

[27] Dr. Goddard testified that the "conscious withholding of unfavorable animal or clinical data" was not a "gray area" (Tr. 6/17/93, p. 74). Dr. Goddard then was asked by plaintiff's counsel: "Do you agree, sir, that the physician no matter how visible cannot protect his patient's safety. But, he has to rely upon the manufacturer for information?" Dr. Goddard answered: "That's not the only source. He relies upon a variety

this testimony was somehow insufficient is bound to generate substantial confusion in future cases.

3. It is settled in the District that the verdict winner is entitled to have the evidence viewed in the light most favorable to the winner. Viewing the evidence in the light most favorable to the plaintiff produces the following facts. *First*, Parafon Forte poses a significant risk of liver damage that was not disclosed in the drug's labeling.[28]

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of sources for information in the treatment of his patient. That's 1 source that he has to rely on – yes." The cross-examination continued:

> Q. Since 1938 at least putting out false and putting out false information in the labeling has not only been immoral but also it has been illegal. Is that a fair statement?
>
> A. **Misbranding is illegal.** You are correct.
>
> Q. In fact, Plaintiff's 35-1 which is in evidence, the Section 352 of the United States Code states in very explicit words, does it not, that a drug or device shall be misbranded if its label is false or misleading in any particular. Is that a fair statement?
>
> A. That's correct.
>
> Q. That means separate. It does not have to be false and misleading. But, it can be false or it can be misleading and in any event, it makes the drug misbranded; is that correct?
>
> A. That's correct, sir.
>
> Q. That's a violation of the Food Drug and Cosmetic Act?
>
> CFR 21 – yes, sir (Tr. 6/17/93, pp. 88-89).

[28] The importance of these finding are reinforced in this case by the extraordinary post-trial occurrence of the FDA granting, in part, a Citizen's Petition which required McNeil to amend its product labeling to include a warning about the risk

Second, Mrs. Gilliam died as a result of liver failure caused by Parafon Forte. *Third,* McNeil knew of the significant risk of liver damage and willfully chose not to include a warning about the risk in the product's labeling. *Fourth,* in deliberately omitting the risk of liver damage from the product's labeling, McNeil acted in reckless disregard of the danger the drug posed to consumers. Each of these findings is supported by testimony of plaintiff's medical experts.[29]

Petitioner urges the Court *en banc* to reconsider whether the record is so lacking in evidence as to require

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of liver damage. This fact was brought to the division's attention by way of a supplemental filing by Petitioner.

[29] Even if the negligence standard is found to govern this case, an order reversing and mandating entry of judgment for McNeil should be reviewed by the entire court. The division misconstrued a concession made by counsel at oral argument, namely that the only evidence of standard of care was the Act and its implementing regulations, treating this as an admission that there is no expert testimony in support of any of Mrs. Hawkins' specific claims of negligence. That is not true. Plaintiff's experts were improperly precluded by the trial court from expressing opinions explicitly stating that McNeil violated the standard of care, because the trial court apparently viewed that as the ultimate question for the jury to decide. However, plaintiff's experts did express opinions that the drug's labeling had an inadequate warning and that McNeil intentionally or recklessly misled the medical community. Indeed, the division's opinion acknowledges such testimony in its summary of the case, even though it fails to recognize the inconsistency between its summary of the facts and its erroneous conclusion. However, what the division's opinion does assert, in conflict with its own summary, is that the only evidence of standard of care was the Act and its regulations. Petitioner submits that such a view is patently inaccurate.

an order overruling the verdict and mandating entry of judgment for the defendant. The duty of the drug company to provide an adequate warning is mandated by both the Act and the common law and, consequently, there is no issue as to what the *standard of care* is in this case.[30] The only issue is whether the company breached the standard. And as to that issue, even the division's opinion acknowledges substantial expert testimony that McNeil provided an inadequate warning to the medical community. A review of the trial transcript, moreover, reveals a great deal of additional expert testimony in support of the jury's finding of a failure to provide an adequate warning and a breach of duty to its consumers.[31] Plaintiff's experts opined that McNeil failed to adequately warn of the risk of liver damage; they explained in great detail why the warning in the labeling was inadequate. The experts provided ample basis for the jury to find a breach of the required standard of care, even *if* such proof is required in a strict liability case.[32]

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[30] Even if the Court *en banc* is inclined to agree with the division that strict liability and negligence are functional equivalents in an inadequate warning case, the issue is too important and potentially confusing to future decision-makers to allow its resolution in the form presented by the opinion in the present case.

[31] *See* 6/1-2/93 Tr., pp. 31, 41-42, 50-51, 73-74, 141-142, 157, and 308-311.

[32] The extraordinary nature of the decision, combined with its wide-ranging impact on law, makes this decision one that merits careful consideration by the entire Court. Indeed, the decision rendered is built on such questionable reasoning and takes such a one-sided view (the view of the verdict loser) of disputed facts that it violates plaintiff's right to a jury trial, due

Conclusion

A review of the briefs and the record in this case by the entire Court will demonstrate that it was a straightforward strict liability and punitive damage case that was hotly contested with numerous well qualified experts testifying for each side. The jury carefully considered all of the evidence and rendered a verdict which the trial judge found supported by evidence and the applicable law. A reversal based on a new and peculiar construction of fundamental tort doctrine should be rendered only after rehearing reargument and careful consideration by the Court *en banc*. Moreover, this decision, if allowed to stand, will have a significant impact on other failure to warn cases – both pharmaceutical cases and non-pharmaceutical cases. Petitioner respectfully requests that this Honorable Court enter an order vacating the division's opinion and directing a rehearing before the entire Court.

Respectfully submitted,

EATON & McCLELLAN

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process and equal protection of the laws as secured by the United States Constitution.

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Certificate of Service

I hereby certify that on this the 6th day of January, 1996, a copy of the foregoing Petition for Rehearing *En Banc* was sent by first class mail, postage prepaid, to:

Richard Dean, Esq.
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/s/ Allen T. Eaton
ALLEN T. EATON

APPENDIX D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 16 1996

Allen T. Eaton
Eaton, McClellan & Allen
1212 New York Avenue, N.W.
Suite 1212
Washington, D. C. 20005

Re: Docket No. 94P-0378/CP1

Dear Mr. Eaton:

This responds to your petition dated October 17, 1994, requesting that the Food and Drug Administration (FDA) remove all drug products containing chlorzoxazone from the market until a full and complete investigation is conducted into alleged false statements in McNeil Pharmaceutical's original new drug application (NDA) for chlorzoxazone tablets. (McNeil Pharmaceutical currently markets chlorzoxazone tablets as Paraflex® in the 250 mg strength, and Parafon Forte® DSC in the 500 mg strength.) You further request that the FDA investigate the hepatic toxicity of chlorzoxazone and, if it determines that chlorzoxazone is a hepatotoxin, that the FDA require that labeling for all drug products containing chlorzoxazone include adequate warnings. For the reasons stated below, your petition is denied in part and granted in part.

Your petition alleges that McNeil Pharmaceutical submitted false and incomplete safety data in its NDA for chlorzoxazone tablets and you request that the agency withdraw approval of the drug until an investigation into the alleged falsification is complete[1] The NDA sponsor denied your allegations in comments submitted to the agency (94P-0378/C1).[2] The FDA takes allegations of falsification of clinical data and other types of application fraud very seriously. The agency has seen that criminal charges were brought against 17 clinical investigators for submitting false data, and convictions were obtained in each case. The agency has also taken administrative action against clinical investigators who have submitted false data; the FDA has disqualified 82 clinical investigators from participation in clinical trials conducted to generate data for use in product approvals by the FDA. The

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[1] Your petition requests that the agency "remove the drug, Parafon Forte DSC, and all chlorzoxazone-containing products from the chain of commerce until such time as a full and complete investigation is conducted on the submission by McNeil Pharmaceutical of false and untrue statements in its original New Drug Application." Petition at 1. Under 21 CFR 314.150(a)(2)(iv), the FDA may initiate proceedings to withdraw approval of an NDA if the agency finds that the application contains any untrue statement of material fact. Thus, the withdrawal of the approval would be the end point of an investigation and administrative proceeding rather than the beginning.

[2] In 1989, McNeil Pharmaceutical transferred the NDAs for Paraflex® and Parafon Forte® DSC to the R.W. Johnson Pharmaceutical Research Institute. McNeil Pharmaceutical continues to market the drugs. Both organizations are divisions of Ortho-McNeil Pharmaceutical Corporation.

ongoing FDA and Department of Justice criminal investigation into application fraud and other wrongdoing in the generic and brand name drug industry has resulted in the conviction of 14 corporations and over 50 individuals.

The FDA has broad discretion in deciding whether or not to bring enforcement actions. This enforcement discretion was recognized by the Supreme Court in *Heckler v. Chaney*, 470 U.S. 821, 831 (1985), where the Court stated "that an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion."[3]

In exercise of its enforcement discretion, the FDA declines to conduct the investigation that you request into the alleged false statements. The agency does so for several reasons. The agency's ability to resolve the controverted facts would be severely hampered because the bulk of the alleged fraud occurred over 35 years ago, with the last instance of alleged fraud occurring on June 14, 1978. Absent new evidence of criminal conduct, criminal prosecution would be barred by the statute of limitations. (See 18 U.S.C. 3282.)

Investigations to determine whether civil or administrative enforcement action should be taken against the drug

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[3] Lower courts have consistently given *Heckler v. Chaney* its intended broad reading. For example, in *Community Nutrition Inst. v. Young*, 818 F.2d 943, 950 (D.C. Cir. 1987), the court stated that "FDA enjoys complete discretion not to employ the enforcement provisions of the [Federal Food, Drug, and Cosmetic Act (the act)]. . . . " The court in *Heterochemical Corp. v. FDA*, 644 F.Supp. 271, 274 (E.D.N.Y. 1986) held that " . . . FDA is not required to investigate possible violations of the [act]."

products or the NDAs for the drug products would also be inappropriate. The FDA has reviewed data contained in the NDAs that have not been the subject of allegations of fraud, as well as published data and adverse drug experience reports available to the FDA. The agency has determined that the data do not currently support the FDA reversing its determination that chlorzoxazone is a reasonably safe and effective drug when used in accordance with its approved labeling and the removing the drug from the market would not be in the interest of the public health.

The NDAs for chlorzoxazone were submitted to the agency and the drug first went on the market in 1957 and 1958. At that time, under section 505 of the Federal Food, Drug, and Cosmetic Act of 1938 (Pub. L. 75-717), NDAs were not affirmatively approved; rather, they went into effect if the FDA did not disapprove the application. The Drug Amendments of 1962 (1962 amendments) (Pub. L. 87-781) provided for the first time that the agency affirmatively approve NDAs. However, before the 1962 amendments went into effect, sponsors of NDAs were only required to submit data demonstrating the safety of a drug product. The 1962 amendments provided that NDAs that had become effective before October 10, 1962, would be deemed to be approved if, as with drugs approved after October 10, 1962, the drugs were shown to be effective for their intended use.

Consequently, the FDA initiated a program to evaluate the drugs that had been deemed approved to determine whether there was substantial evidence of their effectiveness. This systematic evaluation and the implementation of FDA's findings became known as the Drug Efficacy

Study Implementation or DESI. Chlorzoxazone was the subject of a DESI proceeding, where data on the effectiveness of chlorzoxazone were submitted to the agency, and the agency, on the basis of that information and other available information, determined that chlorzoxazone is effective for the relief of acute, painful musculo-skeletal conditions. (See the *Federal Register* of August 15, 1974 (39 FR 29398).)

Even the Powers' article, which you cite in your petition, describes chlorzoxazone as "usually safe" and does not recommend that doctors cease from prescribing the drug, merely that doctors should be cognizant of and monitor possible hepatotoxicity. (See Powers et al., "Chlorzoxazone Hepatotoxic Reactions: An Analysis of 21 Identified or Presumed Cases," 146 *Arch Int Med*, 1183, 1186 (1986).)

You further request that the FDA investigate the hepatic toxicity of chlorzoxazone and, if the agency determines that chlorzoxazone is a hepatotoxin, that the FDA require adequate warning statements on the labeling. After conducting such an investigation, the FDA has determined that chlorzoxazone can demonstrate hepatocellular toxicity. After consulting with the FDA, the R.W. Johnson Pharmaceutical Research Institute submitted supplements to its NDAs for Paraflex® and Parafon Forte® DSC to delete the paragraph in the adverse reactions section of the labeling describing possible hepatic injury (which you state in your petition to be inadequate) and insert the following warning in the labeling for these drugs:

> Serious (including fatal) hepatocellular toxicity has been reported rarely in patients receiving chlorzoxazone. The mechanism is unknown but

> appears to be idiosyncratic and unpredictable. Factors predisposing patients to this rare event are not known. Patients should be instructed to report early signs and/or symptoms of hepatotoxicity such as fever, rash, anorexia, nausea, vomiting, fatigue, right upper quadrant pain, dark urine, or jaundice. Chlorzoxazone should be discontinued immediately and a physician consulted if any of these signs or symptoms develop. Chlorzoxazone use should also be discontinued if a patient develops abnormal liver enzymes (eg.[sic] AST, ALT, alkaline phosphatase and bilirubin).
>
> The concomitant use of alcohol or other central nervous system depressants may have an additive effect.

The supplements were submitted by the drug sponsor on October 25, 1994, under 21 CFR 314.70(c)(2)(i), which allows sponsors to change labeling to "add or strengthen a contraindication, warning, precaution, or adverse reaction" without the FDA's prior approval. The agency reviews these supplements, but the sponsor may implement the changes before receiving FDA approval. The agency reviewed the labeling changes submitted by the sponsor, and approved the supplement on January 10, 1995. The FDA has notified applicants who have submitted approved and unapproved abbreviated new drug applications (ANDAs) that refer to Paraflex® and Parafon Forte® DSC as listed drugs (i.e., applications for generic versions of chlorzoxazone tablets) of the changes set out in the R.W. Johnson Pharmaceutical Research Institute's supplements, and that the ANDA applicants should supplement or amend their applications to provide the same warning in their labeling.

The FDA is aware that some prescribing health care professionals do not read the current approved labeling for drug products they may prescribe, particularly when a drug has been on the market for a long time. To help ensure that the revised warnings get the proper attention from health care professionals, the FDA published an article in the January 1996 *FDA Medical Bulletin* containing the revised warning (copy enclosed). The *FDA Medical Bulletin* is distributed by the agency to over one million health care professionals. The FDA also included the revised warning in a column prepared by Stuart L. Nightingale, M.D., the FDA's Associate Commissioner for Health Affairs, which was published in the December 27, 1995, issue of the *Journal of the American Medical Association* (copy enclosed). The agency considers these actions appropriate to ensure that the revised warning attains its maximum effect.

The FDA believes that the foregoing actions satisfy the second request for agency action contained in your petition.

For the reason stated above, your petition is denied in part and granted in part.

Sincerely yours,

/s/ Janet Woodcock
Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

Enclosures

APPENDIX E

RESTATEMENT (SECOND) OF TORTS

§ 288 A. Excused Violations

(1) An excused violation of a legislative enactment or an administrative regulation is not negligence.

(2) Unless the enactment or regulation is construed not to permit such excuse, its violation is excused when

(a) the violation is reasonable because of the actor's incapacity;

(b) he neither knows nor should know of the occasion for compliance;

(c) he is unable after reasonable diligence or care to comply;

(d) he is confronted by an emergency not due to his own misconduct;

(e) compliance would involve a greater risk of harm to the actor or to others.

* * *

Comment:

c. Excuse not permitted. There are statutes which prohibit an act omission under particular circumstances, irrespective of whether the actor knows or could in any possible way learn of the circumstances, or could in any way avoid the act of omission, or may have any other excuse whatever. Thus statutes prohibiting the employment of children below a certain age at or about dangerous machinery usually have been construed to make their employment a crime, and to result in tort liability,

even though the employer does not know and could not possibly learn that the child is below the statutory age. The Federal Safety Appliance Act has been construed to require railroads engaged in interstate commerce to provide safety devices, such as automatic couplers, in good working order, for the protection of their employees, and to permit no excuse because of the failure of the device to operate, or all possible diligence and care to provide it. Such statutes in reality result in strict liability, although the courts have continued to speak of liability for negligence. When they are adopted by the court as defining a standard of conduct for a tort action, the standard adopted is one of strict liability, and the statute is still construed to permit no excuse. On the same basis, a particular statute may be construed not to permit a particular excuse, although it may permit other excuses.

Illustration:

1. A Pure Food Act, which provides that any person selling unwholesome or poisonous food shall be guilty of a crime, is construed to mean that he shall be guilty irrespective of care used in the preparation of the food. A sells to B a turkey sandwich which is contaminated and unwholesome, and as a result B is made ill by food poisoning. A has exercised all possible diligence and care in purchasing the ingredients and preparing the sandwich, and is in no way negligent. A is subject to liability to B under the statute.